DECLARATION CE DE CONFORMITE /
EC DECLARATION OF CONFORMITY

LCH Medical Products, 12-14 rue Sarah Bernhardt – 92600 Asnières-sur-Seine – FRANCE,
assurons et déclarons sous notre seule responsabilité que le dispositif médical /
certify and declare under our sole responsibility that the medical device :

- **SETS DE SOINS DE PANSEMENT ET INSTRUMENTS stériles à usage unique,**
  Voir la liste des produits LCH associée à cette déclaration en annexe
- ***Sterile disposable WOUND CARE KITS AND INSTRUMENTS***
  See List of applicable LCH products related to this declaration

Répond aux exigences essentielles et aux recommandations de la Directive Européenne 93/42/CEE amendée par la Directive 2007/47/CEE et qu'il est en conformité avec l'arrêté du 15 mars 2010 relatif aux dispositifs médicaux /
Is in conformity with the essential requirements and with the recommendations of the Directive 93/42/EC amended by Directive 2007/47/EC and is compliant with the French order of March 15th, 2010 related to medical devices

Les dispositifs médicaux appartiennent à classe Is suivant les règles 1 et 4.
(voir annexe)
Medical device of class Is according to the rules 1 and 4 (see annex)

Cette déclaration est faite sur la base du Certificat N° ECM20MDD17 relatif au marquage CE selon la Directive Européenne 93/42/CEE, Annexe V établi par Ente Certificazione Macchine (ECM) s.r.l Via ca' Bella, 243/A – 40053 Valsamoggia (BO) – Italia,
Organisme notifié N°1282.
This declaration is based on EC Certificate N° ECM20MDD17 related to EC marking according the European Directive 93/42/EC, Annex V issued by Ente Certificazione Macchine (ECM) s.r.l Via ca' Bella, 243/A – 40053 Valsamoggia (BO) – Italia,
Notified body N°1282

Lieu et date d'émission / Place and date of issue
Asnières-sur-Seine, 02/12/2020

Par/by Emmanuelle GARNIER
Directeur Qualité et Affaires Réglementaires / Quality and Regulatory Affairs Manager

Annexe de la déclaration CE de conformité de la gamme de dispositifs médicaux /
Annex of the EC declaration of conformity for the range of medical devices

Sets de soins de pansement et instruments stériles à usage unique / *Sterile disposable wound care kits and instruments*

REFERENCE LCH	Désignation	Règle
DK-40858	Set de pansements/ Dressing Kit	4
DK-40859	Set de pansements/ Dressing Kit	4
DK-40860	Set de pansements/ Dressing Kit	4
DK-40861	Set de pansements/ Dressing Kit	4
DK-801	Set de pansements/ Dressing Kit	4
DK806	Set de pansement/Dressing Kit	4
DK-808E	Set de pansement/Dressing Kit	4
DK-809C	Set de pansement/Dressing Kit	4
DK819	Set de pansement/Dressing Kit	4
DK823	Set de pansement/Dressing Kit	4
DK830	Set de pansement/Dressing Kit	4
DK-837C	Set de pansement/Dressing Kit	4
DK-854	Set de pansement/Dressing Kit	4
DK872	Set de pansement/Dressing Kit	4
DK-874	Set de pansement/Dressing Kit	4
DK-901C	Set de pansement/Dressing Kit	4
DK902	Set de pansement/Dressing Kit	4
DK-903	Set de pansement/Dressing Kit	4
PBS-8200B	Pince anatomique/Anatomical forcep	1
PBS-8300G	Pince anatomique/Anatomical forcep	1
PBS-8349	Pince kocher/Kocher forcep	1
SA-300D	Set de pansement/Dressing Kit	4
SCI-01	Ciseaux bouts pointus/Sharp scissors	1
SCI-02	Ciseaux bouts ronds/Blunt scissors	1
SCI-03	Ciseaux bouts mousses et pointu/Sharp and blunt scissors	1

n. **ECM20MDD17 rev.0**

Data di prima emissione * *Date of first issue*	*10/07/2013*
Data di emissione *Date of issue*	*24/11/2020*
Data di ultimo rinnovo *Date of last renewal*	*24/11/2020*
Data di revisione *Date of revision*	*/*
Data di scadenza *Expiry date*	*27/05/2024*

Certificato CE

EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato V
Issued according to 93/42/EEC directive – Annex V

Richiedente
Applicant

Ragione Sociale *Company Name*	LCH Medical Products
Sede legale *Legal address*	12-14 rue Sarah Bernhardt
Località *Place*	92600, Asnières-sur Seine, France
Sito produttivo *Place of production*	Z.A. Charles de Gaulle – 14, rue Ferdinand de Lesseps, 95190, Goussainville, France
Dispositivo Medico *Medical device*	Disposable sterile care kits and instruments Disposable sterile wound care kits
Identificato come *Identified as*	*See the annex of this certificate*

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità (limitato agli aspetti di fabbricazione relativi alla garanzia ed al mantenimento della sterilità) in accordo all'allegato V della direttiva 93/42/CEE) e ha rilevato che ne soddisfa i requisiti.
Si fa riferimento al rapporto di audit di emissione del presente certificato del 1-3/9/2020; rif. piano di certificazione: Novomed-LCH-19.04

ECM, Notified Body n° 1282 has verified the Quality System (restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions) in accordance with annex V of the 93/42/EEC directive and found that it meets aforesaid requirements.
Reference to the audit report related to issue of the present certificate dated 1-3/9/2020; ref. certification plan: Novomed-LCH-19.04

Firma autorizzata
Authorized signature

(Federica Secchi – Technical Director)

*certificato rilasciato per la prima volta da altro Organismo di Certificazione
certificate issued for the first time by another Certification Body

Questo certificato, compreso l'allegato (se presente), può essere riprodotto solo integralmente e senza alcuna variazione
This certificate, annex included (where applicable), may only be reproduced in its entirety and without any change

n. **ECM20MDD17 rev.0**

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Data di revisione *Date of revision*	*/*
Data di scadenza *Expiry date*	*27/05/2024*

Allegato al Certificato CE

Annex to EC Certificate

Rilasciato i sensi della direttiva 93/42/CEE – Allegato V
Issued according to 93/42/EEC directive – Annex V

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Descrizione ***Description***	**Classe di rischio** ***Risk class***	**Codice NBOG** ***NBOG code***	**Modello** ***Model***	**Taglie** ***Sizes***
DISPOSABLE STERILE CARE KITS AND INSTRUMENTS				
Suture removal kits	Is	MD0301 + MDS7006	**DK-915NT.C**	N.A.
Magill forceps - straight - 170mm	Is	MD0106 + MDS7006	**MTS-08040**	N.A.
Magill forceps - straight - 200mm	Is	MD0106 + MDS7006	**MTS-08041**	N.A.
Magill forceps - straight - 250mm	Is	MD0106 + MDS7006	**MTS-08042**	N.A.
High precision littauer scissors	Is	MD0301 + MDS7006	**SCI-04**	N.A.
Suture removal kits	Is	MD0301 + MDS7006	**DK-9-44612**	N.A.
Metallic staple removers	Is	MD0301 + MDS7006	**MTS-08140**	N.A.
DISPOSABLE STERILE WOUND CARE KITS				
Dressing kit	Is	MD0301 + MDS7006	**DK-801**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK806**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-808E**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-809C**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK819**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK823**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK830**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-837C**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK872**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-874**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-901C**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK902**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-903**	N.A.
Anatomical forcep	Is	MD0301 + MDS7006	**PBS-8200B**	N.A.
Anatomical forcep	Is	MD0301 + MDS7006	**PBS-8300G**	N.A.
Kocher forcep	Is	MD0301 + MDS7006	**PBS-8349**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**SA-300D**	N.A.
Sharp scissors	Is	MD0301 + MDS7006	**SCI-01**	N.A.
Blunt scissors	Is	MD0301 + MDS7006	**SCI-02**	N.A.

n. **ECM20MDD17 rev.0**

Data di prima emissione * *Date of first issue*	*10/07/2013*
Data di emissione *Date of issue*	*24/11/2020*
Data di ultimo rinnovo *Date of last renewal*	*24/11/2020*
Data di revisione *Date of revision*	*/*
Data di scadenza *Expiry date*	*27/05/2024*

Sharp and blunt scissors	Is	MD0301 + MDS7006	**SCI-03**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-40858**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-40859**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-40860**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-40861**	N.A.
Dressing kit	Is	MD0301 + MDS7006	**DK-854**	N.A.

Firma autorizzata
Authorized signature

(Federica Secchi – Technical Director)

Questo allegato può essere riprodotto solo integralmente e senza alcuna variazione, assieme al certificato a cui si riferisce
This Annex may only be reproduced in its entirety and without any change, together with the certificate to which it refers

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/06/03
CL1/V4a

Esteemed

NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France

Notified Body Confirmation Letter Reference: CERBO0330023 Rev.2 and CERBO0350624

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Cermet Italia S.p.a., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France
SRN Number: FR-MF-000022240

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the

devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 05/06/2024 08:23:01

NB 0476

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
/	/	/	/

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Operating scissors 37001494KitCutSkin7N	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Kit For Suture Precisio 1' Kit For Suture "Precision" Micro Halsey Type Needle Holder Set de pose de suture Set de suture Needle holder 37001494KitSutureDeliv85	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Thin Dissecting forcep/ Adson micro forcep/ Micro Adson Dissecting Forcep without tooth/ Ultra thin Dissecting Adson Forcep with tooth/ Ultra thin Dissecting Adson Forcep without tooth 37001494KitTissueClampVA	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Kit for Hypodermic Implant Insertion / Kit for Hypodermic Implant Insertion – Pharmacy 37001494ImplantInserKitFDT	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate N°36982 rev 1. -Addendum n° 36981 rev. 2 Expiry date: 10/09/2023 -GMED N° 0459

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable sterile kits for removal of contraceptive implant/ Kit for hypodermic implant removal Extrimplant kit (for chemist)/ Kit for hypodermic implant removal Extrimplant kit 37001494ImplantRemovKitHT	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate N°36982 rev 1. - Addendum n° 36981 rev. 2 -Expiry date: 10/09/2023 -GMED N° 0459
Suture removal kits 37001494SuturRemSteKitXM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Dressing Kit 37001494WoundDressingB3	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Magill forceps - straight - 170mm Magill forceps - straight - 200mm Magill forceps - straight - 250mm Metallic staple removers 37001494WoundCareKitSte7P	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Metallic staple removers 37001494StapleRemoversA7	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282
Anatomical forcep Kocher forcep 37001494SwabsClampEV	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
GYN&CUBE pessary 37001494pessary82	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-EC certificate n° 36974 rev. 0 Addendum n° 36973 rev. 1 -Expiry date: 10/09/2023 -GMED N° 0459

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Kit for IUD Insertion 37001494InsertIUDKitSteFD	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Evolution double hysterometer 37001494SteKitHysteroMUL	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Cut clamp forceps 37001494ClampCutUmbDM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Long Scissors with Littauer Blades 37001494ScissorCutIUDXD	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Metalic Cheron Forcep Cheron forcep Metallic Bengolea Forcep Evolution forceps 37001494SwabsForcepsPU	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
DIU hook 37001494IUDRemovHookRM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282
Pozzi Forcep pink Metallic Palmer Pozzi Forcep Metallic Pozzi Forcep 37001494PozziUterusU9	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Set de Chirurgie / Kit For Surgery 37001494KitForSurgeryAT	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	-EC certificate n° MED 31033: -Expiry date: 26/05/2024 -KIWA N° 0476
Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision" Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision" 37001494SetinterventionPV	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	-EC certificate n° MED 31033: -Expiry date: 26/05/2024 -KIWA N° 0476
Set d'intervention Gold / Gold Surgery kit 37001494KitForSurgeryAT	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Set de détersion pour plaies chroniques/Cleaning kits for chronic wounds 37001494CleankitswoundW3		Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Pince Halstead courbe sans griffe / Curved Halstead Forcep without tooth Pince Halstead/Halstead forcep 37001494pincechirurgic4Z	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Ciseaux à Dissection Metzenbaum / Metzenbaum Dissection Scissors 37001494KitCutSkin7N	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 -GMED N° 0459 -EC certificate n° MED 31033 -Expiry date: 26/05/2024 -KIWA N° 0476

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Stylet gradué/Graduated stylus 37001494GraduatedstylusJR	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Set d'ablation de Suture Precisio 3' / Kit For Suture Removal Precisio 3' 37001494SuturRemSteKitXM	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Gyn & Push Pince à biopsie du col utérin / Gyn & Push Disposable cervix biopsy forceps 37001494PincebiopsieP9	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
00	2024/06/03	Initial issue
01	2024/06/05	certificate information added

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111

Quotation Code: CERBO0330023 Rev.2

To the kind attention of Jean-Christophe Ferrer
NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France

Granarolo dell'Emilia, 15/05/2024

SUBJECT: QUOTATION FOR CERTIFICATION PURSUANT TO REGULATION (EU) 2017/745

Following your kind request, we are pleased to send you our best quotation, according to the information provided.



We are Kiwa, a global leader in Testing, Inspection and Certification (TIC). With our services, we create Trust in our customers' products, services, processes and (management) systems.

As a Partner for Progress, we do so in a wide variety of market segments, ranging from Oil and Gas to Construction, from Transport to Tourism industry and from Energy to Water, Healthcare, Food, Feed and Farming.

Kiwa employs over 10,000 people in over 40 countries, in Europe, Asia, the Americas and Oceania. Through its network of branches and sales offices, Kiwa offers a complete and widespread service portfolio, taking into account individual customer needs and characteristics, locally as well as internationally.

As Kiwa Italy Group, with 8 Offices and 6 Laboratories, we are among the leading TIC organization operating in Italy.

With best wishes for a fruitful collaboration, yours sincerely.

Alessia Frabetti
Medical Device Division Manager

Trust
Quality
Progress

This quotation is concluded between:

LEGAL COMPANY NAME: NOVOMED GROUP
SINGLE REGISTRATION NUMBER (SRN): FR-MF-000022240
(hereinafter referred to as "Company")

and

Kiwa Cermet Italia S.p.A. (Notified body no. 0476).
Kiwa Cermet Italia cooperates with Kiwa France.
Kiwa France will carry out the commercial activities on behalf of Kiwa Cermet Italia, as established in a specific service agreement.
Kiwa Cermet Italia retains responsibility for all activities contained in this quotation (and the documents referred to therein) and retains the exclusive right on the decisions concerning the certification (including the assignment of the assessment teams).

BINDING ACCEPTANCE OF QUOTATION:

This quotation is based on the data provided by your Company in the form MOD PO 09 MED_MDR dated 16/04/2024
This quotation shall become an official binding contract when your Company returns it duly signed to Kiwa Cermet Italia. The Company hereby acknowledges and accepts that Kiwa Cermet Italia, based on further and/or more in-depth evaluations of the documents provided by the Company and/or further and/or more in-depth information, may – in addition to any other contractual or statutory right or remedy - amend the terms and conditions of this contract or terminate it, in accordance with notes no. 9, 10 and 11 in the section "NOTES" at the bottom of this quotation.

The conditions for certification established by Kiwa Cermet Italia are reported here below:

PRODUCT IDENTIFICATION:

Certification reference standard: Regulation (EU) 2017/745

Sites:

Location type (Legal and operational, Legal, Operational, warehouse)	Address (street, postcode, city, country)	Processes carried out	Number of employees
Legal and operational	12-14 rue Sarah Bernhardt - 92600 Asnières sur Seine- France	Managment -Supplying-purchase-IT-ADV-Marketing	22 of which 1 PT
Operational/ Warehouse	14 rue Ferdinand de Lesseps - 95190 Goussainville - France	QA&RA-design &development - warehouse	19 of which 2 PT

Category of devices subject to certification:

Technical Documents (identification)	EMDN nomenclature	MDR codes – MD category	Device name	BASIC UDI-DI	Class	Rule	Conformity assessment annex
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive	V0199 - Cutting devices, single use-Other	MDN 1208	Operating scissors	37001494KitCutSkin7N	IIa	6	Annex IX - Parts I and III

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Sede Legale: Via Cadriano, 23, 40057 Granarolo dell'Emilia (BO) - Tel +39.051.4593111 Fax +39.051763382 - info@kiwacermet.it - www.kiwa.it
P.I. 00627711203 – C.F. 03502820370 – Capitale Sociale € 1.000.000,00 i.v.

Implant, tissue clamping and cute skin							
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	H900899 Single use instruments for sutures- Other	MDN 1208	Kit For Suture Precisio 1' Kit For Suture "Precision" Micro Halsey Type Needle Holder Set de pose de suture Set de suture Needle holder	37001494KitSutureDeliv85	IIa	6	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	H900899 Single use instruments for sutures- Other	MDN 1208	Thin Dissecting forcep/ Adson micro forcep/ Micro Adson Dissecting Forcep without tooth/ Ultra thin Dissecting Adson Forcep with tooth/ Ultra thin Dissecting Adson Forcep without tooth	37001494KitTissueClampVA	IIa	6	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	V0599 - Clinical Procedures Kits not included on in other classe- Other	MDN 1208	Kit for Hypodermic Implant Insertion / Kit for Hypodermic Implant Insertion - Pharmacy	37001494ImplantInserKitFDT	IIa	6	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	H9080 - Sutures accessories or H9099 Sutures devices - Other	MDN 1208	Disposable sterile kits for removal of contraceptive implant/ Kit for hypodermic implant removal Extrimplant kit (for chemist)/ Kit for hypodermic implant removal Extrimplant	37001494ImplantRemovKitHT	IIa	6	Annex IX - Parts I and III

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			kit				
Sterile disposable wound care kits and instruments	M9099-General and specialist medical devices-Other	MDN 1204	Suture removal kits	37001494SuturRemSteKitXM	Is	1	Annex IX - Parts I and III
Sterile disposable wound care kits and instruments	M9099-General and specialist medical devices-Other	MDN 1204	Dressing Kit	37001494WoundDressingB3	Is	4	Annex IX - Parts I and III
Sterile disposable wound care kits and instruments	M9099-General and specialist medical devices-Other	MDN 1204	Magill forceps - straight - 170mm Magill forceps - straight - 200mm Magill forceps - straight - 250mm Metallic staple removers	37001494WoundCareKitSte7P	Is	5	Annex IX - Parts I and III
Sterile disposable wound care kits and instruments	M9099-General and specialist medical devices-Other	MDN 1204	Metallic staple removers	37001494StapleRemoversA7	Is	1	Annex IX - Parts I and III
Sterile disposable wound care kits and instruments	M9099-General and specialist medical devices-Other	MDN 1204	Anatomical forcep Kocher forcep	37001494SwabsClampEV	Is	1	Annex IX - Parts I and III
GYN&CUBE Pessary	U089005-Pessarians	MDN 1208	GYN&CUBE pessary	37001494pessary82	IIa	5	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Kit for IUD Insertion	37001494InsertIUDKitSteFD	Is	5	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Evolution double hysterometer	37001494SteKitHysteroMUL	Is	5	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Cut clamp forceps	37001494ClampCutUmbDM	Is	1	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Long Scissors with Littauer Blades	37001494ScissorCutIUDXD	Is	5	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Metalic Cheron Forcep Cheron forcep Metallic Bengolea Forcep Evolution	37001494SwabsForcepsPU	Is	5	Annex IX - Parts I and III

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			forceps				
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	DIU hook	37001494IUDRemovHookRM	Is	5	Annex IX - Parts I and III
Disposable sterile kits and instruments	U0899-Gynaecological devices- Other	MDN 1208	Pozzi Forcep pink Metallic Palmer Pozzi Forcep Metallic Pozzi Forcep	37001494PozziUterusU9	Is	5	Annex IX - Parts I and III

During the certification process, if conditions arise whereby the products can no longer be classified as Medical Devices, or do not fall within the scope of Kiwa Cermet Notification, the certification process cannot proceed.

Here below are the stages of the standard process and the associated costs of the certification process for the abovementioned devices, pursuant to Regulation (EU) 2017/745.

TECHNICAL/ECONOMIC TERMS

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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NOTES

This quotation is valid for 3 months.

By signing this quotation:

1. The Company undertakes to send the technical and quality management sysyem documents as set out in point 4.3 of the Regulation RG 01 MED_MDR and in accordance with MDR, Annex IX, paragraph I, points 2.1 and 2.2, and the valid and effective professional/product Insurance Certificate together with its payment receipt, when signing this quotation. Alternatively and only for technical documents of medical devices which are not class III and class IIb implantable (except for those mentioned in MDR, Article 52.4, second paragraph), the Company undertakes to send the abovementioned documents later, according to the following schedule:

quarter	year
Q4	2024

   If such documents are missing, the review of the application (ref. MDR Annex VII – § 4.3) cannot be completed. The Company also acknowledges and accepts that, if the documents are sent later than scheduled above, the application review and each stage of the certification process may be delayed accordingly as well as the earlier termination of this contract pursuant to notes 9, 10 and 11 in the section "NOTES" at the bottom of this quotation.

   Such documents shall be in Italian or English; otherwise, the certification application cannot be accepted.

2. The Company undertakes to allow Kiwa Cermet Italia to act as provided for by Regulation (EU) 2017/745, including the obligation to inform Kiwa Cermet Italia about supervisory reports, Kiwa Cermet Italia's right to suspend, limit or withdraw issued certificates and Kiwa Cermet Italia's duty to fulfil its information obligations.
3. The Company undertakes to comply with the obligations deriving from the quality management system and to ensure its adequate and effective operation throughout the life cycle of the Medical Devices subject to certification.
4. The Company acknowledges and accepts that if the period of validity of the certificate is less than five years, only the technical/economic terms of the relevant periods described in the tables above apply.
5. The Company undertakes to promptly notify Kiwa Cermet of any changes affecting the product or the related quality management system subject to certification.
6. The Company's Legal Representative hereby declares that he/she is aware that the prerequisite to obtain and maintain the certification is the compliance with applicable legal requirements relevant to the certification scope and that such compliance is the Company's responsibility.
7. **For MDs subject to certification the Company declares that:**

   ☒ **it has not submitted any application for the same conformity assessment procedure at the same time**

   ☐ **it withdrew an application from another notified body before such body made a decision on the same conformity assessment procedure, on: _____**

   Notified Body: _____ NB number: _____

   reason for withdrawal: _____

   ☐ **it previously submitted applications for the same conformity assessment procedure which were refused by another notified body, on: _____**

   Notified Body: _____ NB number: _____

   reason for refusal: _____

8. In order to allow unannounced audits, please note that if a visa is required to visit the country where the critical supplier/subsupplier is located, a signed invitation letter shall be provided to Kiwa Cermet to visit the critical supplier/subsupplier at any time, leaving the date of signature and the date of the visit open. If the Organisation prevents unannounced audits from being carried out (ref. RG 01 MED_MDR), all costs incurred by Kiwa Cermet shall be charged to the Organisation and a penalty equal to 30% of the cost of the unannounced audit applies.
9. The Company acknowledges and accepts that this quotation (i) has been prepared on the basis of the documents provided by the Company and (ii) may be revised by Kiwa Cermet Italia based on further and/or more in-depth evaluations, during the document review – under paragraph 4.2.4 of "RG 01 MED_MDR Regulation for the Certification of Medical Devices according to

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Regulation (EU) 2017/745" given to the Company (in the revision in force at the time of acceptance of this quotation) - or during the next stages of document evaluation or audit under paragraphs 4.3 to 4.9 of the aforesaid RG 01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745.

10. In particular, the Company acknowledges and accepts that, once the Company returns this quotation duly signed to Kiwa Cermet Italia, Kiwa Cermet Italia shall start reviewing the documents already provided - as well as any further document and information that shall be provided – by the Company regarding the service application to which this quotation refers, pursuant to the abovementioned paragraph 4.2.4 of "RG 01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745".

11. The Company acknowledges and agrees that, considering the results from the documentation review under note no. 10, Kiwa Cermet Italia - by means of a written communication to the Company - shall be entitled:
    a) to amend the terms and conditions of this quotation, without prejudice to the Company's right to terminate the contract entered into by signing this quotation (hereinafter referred to as "Contract") by and no later than 15 days from the date of communication of such amendments by Kiwa Cermet Italia; or
    b) to terminate the Contract without notice and immediately, if the conditions/capability of providing the service to which this quotation refers are not met due to technical or product safety reasons.

    The Company exempts and holds Kiwa Cermet Italia harmless from any liability connected to and/or deriving from the exercise of any Kiwa Cermet Italia's rights set forth in letters (a) and (b).

12. The Company declares to have received, understand and accept all definitions, standards and technical requirements for the service provision set out in the following documents attached to this quotation, which constitute an integral and essential part thereof:

    - *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* in the revision in force at the time of acceptance of this quotation;
    - *Kiwa Regulation for Certification* in the revision in force at the time of acceptance of this quotation;
    - *RG01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745 in the revision in force at the time of acceptance of this quotation*

13. The Company acknowledges and accepts that all considerations and costs reported in the technical/economic terms are net of VAT and subject to annual updating based on the ISTAT inflation rate of the previous year; moreover, such considerations do not include costs of transfer, travel time, board and lodging of the Auditors necessary for the service provision. The Company shall pay such costs together with the abovementioned considerations to Kiwa Cermet upon completion of the evaluation activities referred to in this quotation.

14. The signatory of this quotation declares that he/she is legally authorised to sign.

Alessia Frabetti
Medical Device Division Manager

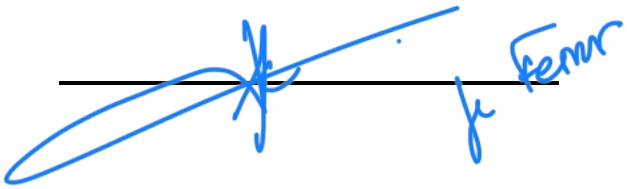


Date, 23/05/2024

Name of the Legal Representative (or duly empowered and authorised representative) in capital letters:

FERRER JEAN-CHRISTOPHE

Stamp and Signature:



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SPECIFIC APPROVAL

Pursuant to and by effect of Articles 1341 and 1342 of the Italian Civil Code, the Company hereby declares that it specifically approves:

- the following provisions according to the section "Notes" of this quotation: notes 9 and 10 (Quotation review), note 11 (Right of unilateral modification to the Contract by Kiwa Cermet Italia and right of termination by the Company – Early termination of the Contract by Kiwa Cermet Italia – Release and hold harmless from and against liabilities);
- *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* in the revision in force at the time of acceptance of this quotation: Article **6** – Responsibility; Article**15** – Termination, interruption or extension of the Contract; Article **16** – Express Termination Clause; Article **18** – Disputes, applicable law;
- *Kiwa Regulation for Certification* in the revision in force at the time of acceptance of this quotation: **4**. Initial Certification: Article 4.1; **5**. Maintaining Certification: Articles 5.1, 5.8; **6**. Suspending or withdrawing certification and reducing the scope of certification: Articles 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8; **7**. Changes to Conformity Assessment Scheme requirements: Articles 7.1, 7.2, 7.3, 7.4; **8**. Use of certificates, certification marks, logos and pictograms: Article 8.4; **10**. Complaints and appeals: Articles 10.1; 10.2; 10.3; 10.4; **12**. Amendment clause: Article 12.1;
- *RG01 MED_MDR Regulation for the Certification of Medical Devices pursuant to Regulation (EU) 2017/745* in the revision in force at the time of acceptance of this quotation: *Articles:* **2.** General principles and guarantees for the customer, letter e); **4** Requirements of the conformity assessment process: art. 4.2.4; **7**. Suspension, withdrawal or reduction of the certification, **8**. Use of the certification, certificate and CE marking, **9**. Complaints, appeals and disputes, **10.** Unilateral modification of the Contract, **11**. Right of unilateral withdrawal from the contract.

Stamp and signature of the Legal Representative (or duly empowered and authorised representative)

Kiwa Cermet Italia S.p.a. with registered office in Granarolo dell'Emilia (Bologna), Italy, Via Cadriano No. 23, VAT No. 00627711203, in its capacity as Data Controller of your personal data, requests your consent to allow us to promote the services provided by Kiwa Group companies, to which Kiwa Cermet Italia S.p.a. belongs, via e-mail (including the subscription to our newsletter), fax and/or SMS, as well as to perform market researches. Your consent to the processing of your personal data is optional and therefore revocable at any time by sending a written communication to Kiwa Cermet Italia S.p.a. via e-mail to: privacy.italy@kiwa.com., or by registered letter with return receipt.

I expressly consent to the processing of my personal data for the marketing purposes described in the privacy policy attached to this agreement, which I declare to have read and understood.

Stamp and signature of the Legal Representative (or delegated person)

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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Privacy Policy pursuant to Article 13 of Regulation (EU) 2016/679

Dear Customer,

Kiwa Cermet Italia S.p.a., in the person of its legal representative *pro tempore*, with registered office in Granarolo dell'Emilia (Bologna), Italy, Via Cadriano No. 23, VAT No. 00627711203, in its capacity as Data Controller, informs you, pursuant to Article 13 of Regulation (EU) 2016/679, that the personal data provided by you on a voluntary basis, shall be subject to processing based on the principles of correctness, lawfulness, transparency, protection of privacy and of your rights, in full compliance with current legislation on the protection of personal data.

1. Data Controller

The Data Controller is Kiwa Cermet Italia Spa, with registered office in Granarolo dell'Emilia (BO), Italy, Via Cadriano 23, certified e-mail: kiwa@pec.kiwaitalia.com.

2. Purpose and legal basis of the data processing

In accordance with the provisions of Article 6 paragraph 1, letters a) and b) of Regulation (EU) 2016/679, the processing of your personal data aims at: i) executing the contract stipulated between the parties or executing pre-contractual measures; ii) fulfilling any related legal obligations; iii) promoting and selling services provided by Kiwa Group Companies, to which Kiwa Cermet Italia Spa belongs, via e-mail (including the subscription to our newsletter), fax and/or SMS; iv) carrying out market researches.

3. Provision of personal data

The Data Controller specifies that:

- with reference to the purposes set out in the aforementioned Article 2 nos. i) and ii), the provision of your personal data is mandatory in order to start the contractual relationship and therefore, failing to provide personal data or providing them partially or inaccurately may consequently result in the non-execution of the contract.
- with reference to the purposes set out in the aforementioned Article 2 nos. III) and iv), the provision of your personal data is not mandatory and therefore, the processing requires your explicit approval. The consent to the use of personal data for marketing purposes is optional and therefore revocable at any time, by sending a written notice to the Data Controller using the contact details specified at the bottom of this Privacy Policy.

4. Data processing methods and duration

You personal data shall be processed at the Data Controller's premises, electronically or in paper format, through the data organisation and processing, for the purposes set out in Article 2) and in any case backed by guarantees of data security and privacy, in full compliance with the applicable technical and organisational measures pursuant to Article 32 of Regulation (EU) 2016/679.

Kiwa specifies that your personal data, acquired for the purposes referred to in the aforementioned Article 2 nos. i) and ii) shall be processed for as long as necessary in order to pursue the purposes specified therein; such data shall be deleted or stored anonymously for statistical purposes after a period of 10 years from the termination of the contractual relationship, without prejudice to compliance with the data retention obligations established by law. With regard to the purposes referred to in Article 2 nos. iii) and iv), Kiwa shall process your personal data and send commercial communications as long as the interruption of promotional activities is not requested by you, in accordance with the retention periods established by law.

5. Communication to third parties

The personal data you provide may be disclosed to: i) public, institutional or professional entities entitled by law to request data acquisition and, exclusively for the purposes set out in Article 2); ii) companies within the Kiwa Group, established within the European Union and included in the lists published by Kiwa Italia Holding Srl; iii) professionals or third party companies (including, for accredited schemes, Accredia and other accrediting and/or notifying bodies), established within the European Union, on which Kiwa relies for the provision of its services. It is hereby specified that the "third party companies" referred to in point iii) have the role of Data Processors in accordance with the provisions of Article 28 of Regulation (EU) 2016/679, and consequently guarantee, under a specific contractual agreement, full compliance with current legislation on the protection of personal data. Should you wish to obtain further information on the subjects listed in the items ii) and iii) of this Article, you may contact the Data Controller using the contact details specified at the bottom of this Privacy Policy.

6. Rights of the Data Subjects

In accordance with the provisions of Articles 15 et seq. of Regulation (EU) 2016/679 you may, at any time, exercise your rights with respect to the Data Controller to: a) access your personal data and obtain a copy thereof; b) request the correction of your data, where the data is inaccurate, or the integration of your data, where the data is incomplete; c) delete your data, in the cases provided for by Article 17 of Regulation (EU) 2016/679; d) limit the processing of your data, in the cases provided for by Article 18 of Regulation (EU) 2016/679; e) receive your personal data in a structured, commonly used and machine-readable format, as well as the right to transmit such data, by Kiwa, to another Data Controller; f) object, at any time, to the processing of your personal data for direct marketing purposes; g) submit a complaint to the Authority for the Protection of Personal Data, pursuant to Article 77 of Regulation EU 2016/679.

For the purposes of exercising the rights referred to in Article 15 et seq. of Regulation (EU) 2016/679, please contact Kiwa Cermet Italia spa, with registered office in Granarolo dell'Emilia (BO), Italy, Via di Cadriano No. 23, 40057, or send an e-mail to privacy.italy@kiwa.com.

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Quotation Code: CERBO0330023 Rev.2

To be filled in by the Customer

IDENTIFICATION DATA:

Name/Company name: Novamed group

Registered office: 12-14 rue Sarah Bernardt

Address (if different from the registered office): 12-14 Asnieres Sur Seine FRANCE

VAT No.: FR85 392 403 986 **Tax code:**

Person responsible for communicating with Certification Body: FERRER Jean christophe

E-mail address: jc.ferrer@novomedgroup.com

Invoices shall be addressed to: Novamedgroup

Invoices shall be sent to: Jean-christophe Ferrer

Phone: +33676059114 Fax: E-mail: jc.ferrer@novamedgroup.com

IBAN code: FR7630027175030002051190111

DATA FOR ELECTRONIC INVOICING:

Select *applicable options* and report the *requested data*:

Public administration: Yes ☐

No ☐

☐ Recipient code:……

☐ Certified e-mail address:……

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Quotation Code: CERBO0350624

To the kind attention of Jean-Christophe Ferrer
NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France

Granarolo dell'Emilia, 17/05/2024

SUBJECT: QUOTATION FOR EXTENSION PURSUANT TO REGULATION (EU) 2017/745

Following your kind request, we are pleased to send you our best quotation, according to the information provided.



We are Kiwa, a global leader in Testing, Inspection and Certification (TIC). With our services, we create Trust in our customers' products, services, processes and (management) systems.

As a Partner for Progress, we do so in a wide variety of market segments, ranging from Oil and Gas to Construction, from Transport to Tourism industry and from Energy to Water, Healthcare, Food, Feed and Farming.

Kiwa employs over 10,000 people in over 40 countries, in Europe, Asia, the Americas and Oceania. Through its network of branches and sales offices, Kiwa offers a complete and widespread service portfolio, taking into account individual customer needs and characteristics, locally as well as internationally.

As Kiwa Italy Group, with 8 Offices and 6 Laboratories, we are among the leading TIC organization operating in Italy.

With best wishes for a fruitful collaboration, yours sincerely.

Alessia Frabetti
Medical Device Division Manager

Alessia Frabetti

Trust
Quality
Progress

Quotation Code: CERBO0350624

This quotation is concluded between:

LEGAL COMPANY NAME: NOVOMED GROUP
SINGLE REGISTRATION NUMBER (SRN): FR-MF-000022240
(hereinafter referred to as "Company")

and

Kiwa Cermet Italia S.p.A. (Notified body no. 0476).
Kiwa Cermet Italia cooperates with Kiwa France.
Kiwa France will carry out the commercial activities on behalf of Kiwa Cermet Italia, as established in a specific service agreement.
Kiwa Cermet Italia retains responsibility for all activities contained in this quotation (and the documents referred to therein) and retains the exclusive right on the decisions concerning the certification (including the assignment of the assessment teams).

BINDING ACCEPTANCE OF QUOTATION:

This quotation is based on the data provided by your Company in the form MOD PO 09 MED_MDR dated 13/05/2024
This quotation shall become an official binding contract when your Company returns it duly signed to Kiwa Cermet Italia. The Company hereby acknowledges and accepts that Kiwa Cermet Italia, based on further and/or more in-depth evaluations of the documents provided by the Company and/or further and/or more in-depth information, may – in addition to any other contractual or statutory right or remedy - amend the terms and conditions of this contract or terminate it, in accordance with notes no. 9, 10 and 11 in the section "NOTES" at the bottom of this quotation.

The conditions for certification established by Kiwa Cermet Italia are reported here below:

PRODUCT IDENTIFICATION:

Certification reference standard: Regulation (EU) 2017/745

Sites:

Location type (Legal and operational, Legal, Operational, warehouse)	Address (street, postcode, city, country)	Processes carried out	Number of employees
Legal and operational	12-14 rue Sarah Bernhardt - 92600 Asnières sur Seine- France	Managment -Supplying-purchase-IT-ADV-Marketing	22 of which 1 PT
Operational/ Warehouse	14 rue Ferdinand de Lesseps - 95190 Goussainville - France	QA&RA-design &development - warehouse	19 of which 2 PT

Category of devices subject to certification:

Technical Documents (identification)	EMDN nomenclature	MDR codes – MD category	Device name	BASIC UDI-DI	Class	Rule	Conformity assessment annex
Sterile disposable kits for suture delivery, for insertion	V9012 - NON SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE USE	MDN 1208	Set de Chirurgie / Kit For Surgery	37001494KitForSurgeryAT	IIa	4	Annex IX - Parts I and III

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and removal of contraceptive Implant, tissue clamping and cute skin							
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	V9012 - NON SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE USE	MDN 1208	Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision" Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision"	37001494SetinterventionPV	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	V9012 - NON SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE USE	MDN 1208	Set d'intervention Gold / Gold Surgery kit	37001494KitForSurgeryAT	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	V9012 - NON SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE USE	MDN 1208	Set de détersion pour plaies chroniques/Cleaning kits for chronic wounds	37001494CleankitswoundW3	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for	V901699 - SPECIALIST SURGICAL INSTRUMENTS AND KITS	MDN 1208	Pince Halstead courbe sans griffe / Curved Halstead Forcep without tooth	37001494pincechirurgic4Z	IIa	4	Annex IX - Parts I and III

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insertion and removal of contraceptive Implant, tissue clamping and cute skin	NOT INCLUDED IN OTHER CLASSES, SINGLE USE-OTHER		Pince Halstead/Halstead forcep				
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	V0199 - CUTTING DEVICES , SINGLE USE - OTHER	MDN 1208	Ciseaux à Dissection Metzenbaum / Metzenbaum Dissection Scissors	37001494KitCutSkin7N	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	M0499-SPECIAL DRESSING - OTHER	MDN 1208	Stylet gradué/Graduated stylus	37001494Graduatedstylus JR	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant, tissue clamping and cute skin	M9099-GENERAL AND SPECIALIST MEDICAL DEVICES - OTHER	MDN 1208	Set d'ablation de Suture Precisio 3' / Kit For Suture Removal Precisio 3'	37001494SuturRemSteKit XM	IIa	4	Annex IX - Parts I and III
Sterile disposable kits for suture delivery, for insertion and removal of contraceptive Implant,	A010201 - NEEDLS AND KITS - HISTOLOGIC AL AND CYTOLOGICA L BIOPSY OF THE SOFT TISSUES	MDN 1208	Gyn & Push Pince à biopsie du col utérin / Gyn & Push Disposable cervix biopsy forceps	37001494PincebiopsieP9	IIa	4	Annex IX - Parts I and III

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force at the time of acceptance of this quotation) - or during the next stages of document evaluation or audit under paragraphs 4.3 to 4.9 of the aforesaid RG 01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745.

10. In particular, the Company acknowledges and accepts that, once the Company returns this quotation duly signed to Kiwa Cermet Italia, Kiwa Cermet Italia shall start reviewing the documents already provided - as well as any further document and information that shall be provided – by the Company regarding the service application to which this quotation refers, pursuant to the abovementioned paragraph 4.2.4 of "RG 01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745".

11. The Company acknowledges and agrees that, considering the results from the documentation review under note no. 10, Kiwa Cermet Italia - by means of a written communication to the Company - shall be entitled:
    a) to amend the terms and conditions of this quotation, without prejudice to the Company's right to terminate the contract entered into by signing this quotation (hereinafter referred to as "Contract") by and no later than 15 days from the date of communication of such amendments by Kiwa Cermet Italia; or
    b) to terminate the Contract without notice and immediately, if the conditions/capability of providing the service to which this quotation refers are not met due to technical or product safety reasons.

    The Company exempts and holds Kiwa Cermet Italia harmless from any liability connected to and/or deriving from the exercise of any Kiwa Cermet Italia's rights set forth in letters (a) and (b).

12. The Company declares to have received, understand and accept all definitions, standards and technical requirements for the service provision set out in the following documents attached to this quotation, which constitute an integral and essential part thereof:

    - *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* in the revision in force at the time of acceptance of this quotation;
    - *Kiwa Regulation for Certification* in the revision in force at the time of acceptance of this quotation;
    - *RG01 MED_MDR Regulation for the Certification of Medical Devices according to Regulation (EU) 2017/745 in the revision in force at the time of acceptance of this quotation*

13. The Company acknowledges and accepts that all considerations and costs reported in the technical/economic terms are net of VAT and subject to annual updating based on the ISTAT inflation rate of the previous year; moreover, such considerations do not include costs of transfer, travel time, board and lodging of the Auditors necessary for the service provision. The Company shall pay such costs together with the abovementioned considerations to Kiwa Cermet upon completion of the evaluation activities referred to in this quotation.

14. The signatory of this quotation declares that he/she is legally authorised to sign.

Alessia Frabetti
Medical Device Division Manager
Alessia Frabetti

Date, 23/05/2024

Name of the Legal Representative (or duly empowered and authorised representative) in capital letters:

FERRER JEAN-CHRISTOPHE

Stamp and Signature:

Je Ferrer

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SPECIFIC APPROVAL

Pursuant to and by effect of Articles 1341 and 1342 of the Italian Civil Code, the Company hereby declares that it specifically approves:

- the following provisions according to the section "Notes" of this quotation: notes 9 and 10 (Quotation review), note 11 (Right of unilateral modification to the Contract by Kiwa Cermet Italia and right of termination by the Company – Early termination of the Contract by Kiwa Cermet Italia – Release and hold harmless from and against liabilities);
- *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* in the revision in force at the time of acceptance of this quotation: Article **6** – Responsibility; Article**15** – Termination, interruption or extension of the Contract; Article **16** – Express Termination Clause; Article **18** – Disputes, applicable law;
- *Kiwa Regulation for Certification* in the revision in force at the time of acceptance of this quotation: **4**. Initial Certification: Article 4.1; **5**. Maintaining Certification: Articles 5.1, 5.8; **6**. Suspending or withdrawing certification and reducing the scope of certification: Articles 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8; **7**. Changes to Conformity Assessment Scheme requirements: Articles 7.1, 7.2, 7.3, 7.4; **8**. Use of certificates, certification marks, logos and pictograms: Article 8.4; **10**. Complaints and appeals: Articles 10.1; 10.2; 10.3; 10.4; **12**. Amendment clause: Article 12.1;
- *RG01 MED_MDR Regulation for the Certification of Medical Devices pursuant to Regulation (EU) 2017/745* in the revision in force at the time of acceptance of this quotation: *Articles:* **2.** General principles and guarantees for the customer, letter e); **4** Requirements of the conformity assessment process: art. 4.2.4; **7**. Suspension, withdrawal or reduction of the certification, **8**. Use of the certification, certificate and CE marking, **9**. Complaints, appeals and disputes, **10.** Unilateral modification of the Contract, **11**. Right of unilateral withdrawal from the contract.

Stamp and signature of the Legal Representative (or duly empowered and authorised representative)

Kiwa Cermet Italia S.p.a. with registered office in Granarolo dell'Emilia (Bologna), Italy, Via Cadriano No. 23, VAT No. 00627711203, in its capacity as Data Controller of your personal data, requests your consent to allow us to promote the services provided by Kiwa Group companies, to which Kiwa Cermet Italia S.p.a. belongs, via e-mail (including the subscription to our newsletter), fax and/or SMS, as well as to perform market researches. Your consent to the processing of your personal data is optional and therefore revocable at any time by sending a written communication to Kiwa Cermet Italia S.p.a. via e-mail to: privacy.italy@kiwa.com., or by registered letter with return receipt.

I expressly consent to the processing of my personal data for the marketing purposes described in the privacy policy attached to this agreement, which I declare to have read and understood.

Stamp and signature of the Legal Representative (or delegated person)

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