WI-EU-REG-021-F131

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY	Revision: 5
	Page: 1 of 1

Wir / We

Name + Adresse der Firma: Name + address of manufacturer:	**Ecolab Deutschland GmbH** **Ecolab-Allee 1** **40789 Monheim am Rhein – Germany** **DE-MF-000004932**

erklären in alleiniger Verantwortung, dass / declare on our own responsibility that

das Medizinprodukt / the medical device	Name / Name **Incidin Alcohol Wipe**
Typ / type	**Incidin™ Alcohol Wipe is a fast acting, ready-to use surface disinfection wipe acc. MDD93/42/EEC: for medical devices.**
Klasse / class gemäß / according	**II a** Anhang IX, Regel 15 / annex IX, rule 15

allen Anforderungen der Richtlinie 93/42/EWG und der EU Verordnung 2023/607 entspricht. /
meets all the provisions of the Directive 93/42/EEC and EU regulation 2023/607.

Angewandte harmonisierte Normen: Applied harmonized standards:	**ISO 14971** **ISO 13485**
Benannte Stelle / Notified body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Deutschland **CE 0297**
Konformitätsbewertungsverfahren Conformity assessment procedure	Artikel 11 Absatz 3a 93/42/EEC gem. Anhang II article 11 paragraph 3a 93/42/EEC acc. to annex II
Konformitätsbestätigung referenz / Conformity reference	002201 MR2
Gültigkeitsdauer / Validity	31.12.2028

Digitally signed by Pouravi Krefting
Date: 2024.05.24 11:00:09 +02'00'

Monheim am Rhein,	**Pouravi Mate / Manager, Regulatory Affairs Healthcare I**
Ort, Datum / place, date	Name und Funktion / name and function

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Medical Device Disinfectants according medical.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	002201 MR2
Certificate unique ID	170774589
Effective date	2021-03-29
Expiry date	2024-05-26
Frankfurt am Main	2021-03-29

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 002201 MR2
Certificate unique ID: 170774589
Effective date: 2021-03-29

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

Device family	Device	Class
Disinfectant for operating theater textiles	Ozonit BNL	IIa
Disinfectant for automated instrument re-processors	Sekumatic FD Sekumatic FDR	IIb
Disinfectant for dialysis machines	Sekumatic FDG Peresal	IIb
Disinfectant for manual re-processing of medical instruments	Sekudrill Sekulyse Sekumed Sekusept aktiv Sekusept easy Sekusept Extra N Sekusept forte Sekusept Plus with variants: PracticeProtect Instrument Disinfection & Cleaning Liquid Glucoprotamin Sekusept Pulver / Poeder / Poudre / Sekusept Pulver classic / Sekupoudre	IIb
Disinfectant for the automated chemo-thermal reprocessing of bed pans	Kodra Des	IIa
Surface disinfectant for medical surfaces and inventory	Incides N Incidin active Incidin Extra N Incidin foam Incidin liquid (Spray) with variants: PracticeProtect Surface Disinfection Alcohol (60%) Spray Incidin OxyDes Incidin Plus Incidin Pro Incidin Rapid Incidin Alcohol Wipe CITROclorex 2% MD	IIa IIa IIa IIa IIa IIa IIa IIa IIa IIa IIa IIa IIa

Annex to certificate
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Ecolab Deutschland GmbH

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40789 Monheim am Rhein
Germany

Device family	Device	Class
Disinfectants for medical surfaces incl. probes	Incidin OxyFoam with variants:	IIb
	PracticeProtect	IIb
	Surface Disinfection Hydrogen Peroxide (1.5%) Foam Spray	
	Incidin OxyFoam S with variants:	IIb
	OXY FOAM WS	IIb
	Incidin OxyWipe with variants:	IIb
	PracticeProtect	IIb
	Surface Disinfection Hydrogen Peroxide (1%) Wipes	
	Incidin OxyWipe S with variants:	IIb
	OXY WIPE WS	IIb
Disinfectant for automated endoscope re-processors	Disinfectant ETD	IIb
	Olympus EndoDis Pro	IIb
Disinfectant for machine preparation of rigid and flexible endoscopes	Olympus EndoDis	IIb
Disinfectant and cleaning agent for dental suction systems	Dekaseptol Gel	IIa
Prion inactivating cleaner for medical Instruments in automated reprocessors	MetalClean	IIb
Detergent and Disinfectant for medical devices	Anios NDT/Sekumatic NDT	IIa
	Actanios LDI/ Sekumatic LDI	IIb

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

Date: 2025-04-01

Notified Body Confirmation Letter
Reference: 1000231461

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, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

SRN: DE-MF-000004932

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH 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 DQS Medizinprodukte GmbH 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,



Lena Breslauer
Regulatory Affairs Manager

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 and Basic UDI-DI (as proposed by the manufacturer within the 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
CITROclorex 2% MD 4028163ED2A422DLI8X	Class IIa	N/A	002201 MR2 (NB 0297)
Incidin active 4028163ED2A442TPOCV	Class IIa	N/A	002201 MR2 (NB 0297)
Incidin Alcohol Wipe 4028163ED2A472DWIBP	Class IIa	N/A	002201 MR2 (NB 0297)
Incidin liquid 4028163ED2A472DLIAN	Class IIa	N/A	002201 MR2 (NB 0297)
Incidin OxyFoam S 4028163ED2B453TLID8	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Incidin OxyWipe S 4028163ED2B453TWIE9	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Incidin Pro 4028163ED2A482TLIDH	Class IIa	N/A	002201 MR2 (NB 0297)
Olympus Disinfectant 4028163ED2B403DLI8Z	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Olympus EndoDis 4028163ED2B433DLIA2	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Olympus EndoDis Pro 4028163ED2B433DLIA2	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Sekusept aktiv 4028163ED2B443TPODM	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Actanios LDI 4028163ED2B493TLIEL	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)
Sekumatic LDI 4028163ED2B493TLIEL	Class IIb excluding Class IIb implantable non-WET	N/A	002201 MR2 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
Anios NDT 4028163ED2A482TLIDH	Class IIa	N/A	002201 MR2 (NB 0297)
Sekumatic NDT 4028163ED2A482TLIDH	Class IIa	N/A	002201 MR2 (NB 0297)

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 and Basic UDI-DI (as proposed by the manufacturer within the 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-27	1000171969	Initial issue
2025-04-01	1000231461	Removal of the following products from Tabel 1: Activator for Sekusept Pulver/Classic, Onzonit BNL and Sekusept Pulver classic.