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Inspire trust.**

TÜV SÜD Product Service GmbH · Germany

Sartorius Stedim Biotech GmbH  
August-Spindler-Straße 11  
37079 Göttingen  
GERMANY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
CBW 075349	0713282871 Höffeler, Bettina	Bettina.hoeffeler@tu- vsud.com	-	2024-04-10	1 of 9

**TÜV SÜD Product Service GmbH  
Confirmation Letter  
CL 075349 0019 Rev. 00**

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000017607

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- If 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
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VAT ID No. DE129484267  
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(Germany) at [tuvsud.com/imprint](https://www.tuvsud.com/imprint)

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Certification Body for Medical Devices  
Ridlerstr. 65  
80339 Munich  
Germany

[tuvsud.com/ps](https://www.tuvsud.com/ps)  
Hotline: +49 89 50084-747

**TUV®**



- 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see [http://www.tuvsud.com/ps-cert?q=cert:CL\\_075349\\_0019\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:CL_075349_0019_Rev.00)

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-04-10

TÜV SÜD Product Service GmbH  
Medical and Health Services

  
Bettina Höffeler (10. April 2024 10:11 GMT+2)

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Bettina Höffeler  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

  
Christian Schroeder (11. April 2024 12:04 GMT+2)

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Dr. Christian Schröder  
Application Reviewer



**Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
<b>Device 1</b>  <b>Minisart HY Zottmann+Stahl 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophobic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 075349 0012 Rev01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 2</b>  <b>Minisart HY, 0.2 µm, Single Use Syringe Filter, Non-Sterile, Hydrophobic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 3</b>  <b>Minisart HY, 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophobic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<b>Device 4</b>  <b>Minisart HY, 0.2 µm, Single Use Syringe Filter, Non-Sterile, Hydrophobic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 5</b>  <b>Minisart NML Gilead, 5 µm, Single Use Syringe Filter, Gamma Sterile, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<b>Device 6</b>  <b>Minisart NML, 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 7</b>  <b>Minisart NML, 0.2 µm, Single Use Syringe Filter, Sterile-R, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 8</b>  <b>Minisart NML, 0.2 µm, Single Use Syringe Filter, Non-Sterile, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<b>Device 9</b>  <b>Minisart NML, 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA#  <input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 10</b>  <b>Minisart NML, 0.45 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 11</b>  <b>Minisart NML, 0.45 µm, Single Use Syringe Filter, Sterile-R, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	<input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 12</b>  <b>Minisart NML, 0.45 µm, Single Use Syringe Filter, Non-Sterile, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 13</b>  <b>Minisart NML, 5 µm, Single Use Syringe Filter, Gamma Sterile, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 14</b>  <b>Minisart NML, 5 µm, Single Use Syringe Filter, Sterile-EO, Non-Pyrogenic, Hydrophili</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows:  G1 075349 0012 Rev. 01 NB 0123  or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	Individual Article number:	<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 15</b>  <b>Minisart Ophthalmic, 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophilic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 16</b>  <b>Minisart SRP Zottmann+Stahl 0.2 µm, Single Use Syringe Filter, Sterile-E0, Non-Pyrogenic, Hydrophobic</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 075349 0012 Rev. 01 NB 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Device 17</b>  <b>Minisart SRP, 0.2 µm, Single Use Syringe Filter,</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A  or	<input checked="" type="checkbox"/> Certification as follows: G1 075349 0012 Rev. 01 NB 0123  or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<b>Sterile-E0, Non-Pyrogenic, Hydrophobic</b>	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

### Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/10	713282871	Initial issue



## Form B: Declaration of Conformity - Europe

GI-105B-00

Effective date: 2022-04-30

Regulation (EU) 2023/607

Minisart® NML | Ophthalsart, Minisart HY | SRP, Minisart NML

### Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

#### Manufacturer

Name: Sartorius Stedim Biotech GmbH

Address: August-Spindler-Straße 11, 37079 Göttingen,  
Germany

Website: [www.sartorius.com](http://www.sartorius.com)

SRN/Actor ID: DE-MF-000017607

#### Authorised Representative

Name: N.A.

Address: N.A.

SRN/Actor ID: N.A.

TÜV SÜD Product Service GmbH

Ridlerstraße 65

80339 München

Germany

#### Notified Body

#### Confidential Material

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## Form B: Declaration of Conformity - Europe

GI-105B-00

Effective date: 2022-04-30

Regulation (EU) 2023/607

Minisart® NML | Ophthalsart, Minisart HY | SRP, Minisart NML

Registration Number of Notified Body	CE 0123
Registration number of certificate issued by Notified Body	G1 0753490012 Rev.01
Validity of certificate issued by Notified Body	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above or in the attached schedule

Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

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## Form B: Declaration of Conformity - Europe

GI-105B-00

Effective date: 2022-04-30

Regulation (EU) 2023/607

Minisart® NML | Ophthalmart, Minisart HY | SRP, Minisart NML

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and the conformity assessment according to Medical Device Regulation (EU) 2017/745 per Annex IX (IX – Chapters I and III), including an assessment of the technical documentation as specified in Annex IX section 4 of at least one representative device for each category of devices, is currently ongoing.

➤ **Quality Management System (QMS)**


A notified body has issued the attached certificate for the MDR-compliant QMS (Q5 075349 0013 Rev. 02).

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Goettingen, 2024-05-16



Dr. Helge Henning  
Managing Director



Dr. Anna Vreemann  
Person Responsible for  
Regulatory Compliance  
prrc-st@sartorius.com

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## Form B: Declaration of Conformity - Europe

GI-105B-00

Effective date: 2022-04-30

Regulation (EU) 2023/607

Minisart® NML | Ophthalmart, Minisart HY | SRP, Minisart NML

### Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (device reference number (device family))	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device
16534-----K (Minisart NML   Ophthalmart)	G1 0753490012 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany  CE0123	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany  CE0123	2028-12-31	N.A.
16534-----GUK (Minisart NML   Ophthalmart)						
16534-----Q (Minisart NML   Ophthalmart)						
17597-----K (Minisart NML   Ophthalmart)						
17597-----Q (Minisart NML   Ophthalmart)						
17528-----K (Minisart NML   Ophthalmart)						
16555-----K (Minisart NML   Ophthalmart)						
16555-----GUK						

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## Form B: Declaration of Conformity - Europe

GI-105B-00

Effective date: 2022-04-30

Regulation (EU) 2023/607

Minisart® NML | Ophthalmart, Minisart HY | SRP, Minisart NML

(Minisart NML   Ophthalmart)						
16555-----Q (Minisart NML   Ophthalmart)						
17598-----K (Minisart NML   Ophthalmart)						
17598-----Q (Minisart NML   Ophthalmart)						
16596-----HYK (Minisart HY   SRP)						
16596-----HYQ (Minisart HY   SRP)						
16596-----ZSK (Minisart HY   SRP)						
16599-----HYQ (Minisart HY   SRP)						
17575-----ACK (Minisart HY   SRP)						
17575-----ZSK (Minisart HY   SRP)						
17594-----K (Minisart NML)						
17594----- GUR(Minisart NML)						
17594----- GJR(Minisart NML)						

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