



**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

Alcon Laboratories, Inc.
6201 South Freeway
76134-2099 FORT WORTH,
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
20895	713282895, 713307489, 713304919, 713307490			2024-05-13	1 of 15

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 020895 0406 Rev. 00**

Reference: 713282895, 713307489, 713304919, 713307490

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: US-MF-000016248

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 TÜV SÜD Product Service 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

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

TÜV SÜD Product Service GmbH
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747

TUV®



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
- 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 www.tuvsud.com/ps-cert?q=cert:CL_020895_0406_Rev._00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-13

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

A black rectangular redaction box covering the signature of Francesco Bianchi.

[Francesco Bianchi \(May 13, 2024 14:21 GMT+8\)](#)

Francesco Bianchi
Conformity Assessment Responsible (CARE)

A black rectangular redaction box covering the signature of Polyana Vilela Heimes.

[Polyana Vilela Heimes \(May 13, 2024 11:46 GMT+8\)](#)

Polyana Vilela Heimes
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
Device Name: Cellugel Ophthalmic Viscosurgical Device BUDI: 038065GMN000005GM	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: ProVisc Ophthalmic Viscosurgical Device BUDI: 038065GMN000009GV	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: BSS Sterile Irrigating Solution BUDI: 038065GMN000011GG	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: IOL WEB-BASED CALCULATORS BUDI: 038065GMN000018GW	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input checked="" 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and Alcon Incisional Safety Knives (Cutting Instruments) BUDI: 038065GMN000023GP	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and	<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: Certificate G1 020895 0393 Rev. 00



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
Alcon Incisional Safety Knives (Cutting Instruments) BUDI: 038065GMN000024GR		<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and Alcon Incisional Safety Knives (Cutting Instruments) BUDI: 038065GMN000026GV	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and Alcon Incisional Safety Knives (Sharps Protection for Incisional Instruments) BUDI: 038065GMN000027GX	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and Alcon Incisional Safety Knives (Sharps Protection for Incisional Instruments) BUDI: 038065GMN000028GZ	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Incisional Instruments and Alcon Incisional Safety Knives (Sharps Protection for Incisional Instruments) BUDI: 038065GMN000029H3	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Compressed Cellulose Devices BUDI: 038065GMN000035GW	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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
Device Name: Alcon Cannulas and Cystitomes (blunt needles) BUDI: 038065GMN000042GT	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Cannulas and Cystitomes (needles) BUDI: 038065GMN000043GV	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Cannulas and Cystitomes (ophthalmic infusion/aspiration) BUDI: 038065GMN000044GX	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Cannulas and Cystitomes (ophthalmic infusion/aspiration) BUDI: 038065GMN000046H3	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Cannulas and Cystitomes (ophthalmic infusion/aspiration) BUDI: 038065GMN000047H5	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: BSS Plus Sterile Irrigating Solution BUDI: 038065GMN000052GW	<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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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
Device Name: Monarch IOL Delivery System (Handpiece) BUDI: 038065GMN000063H3	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Monarch IOL Delivery System (Cartridge) BUDI: 038065GMN000064H5	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: CONSTELLATION TABLETOP BUDI: 038065GMN000067HB	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Constellation Fragmentation Pak BUDI: 038065GMN000072H4	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: UltraVit 20 GA, 5000 CPM BUDI: 038065GMN000073H6	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: PurePoint Laser System BUDI: 038065GMN000074H8	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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 with measuring function	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: PurePoint Laser Indirect Ophthalmoscope (LIO) BUDI: 038065GMN000075HA	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Silicone I/A Tip, Bent BUDI: 038065GMN000079HJ	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: I/A Tip 0.3 mm Small Bore, .033" OD BUDI: 038065GMN000080H3	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: SYSTANE Lubricant Eye Drops FID 102344 BUDI: 038065GMN000084HB	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: SYSTANE HYDRATION Lubricant Eye Drops FID 121843 BUDI: 038065GMN000088HK	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: AOSEPT PLUS w/HydraGlyde FID 120947A	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00



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
BUDI: 038065GMN000097HL	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	TÜV SÜD Product Service GmbH
Device Name: Air Optix plus HydraGlyde (Iotrafalcon B) BUDI: 038065GMN000111GM	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Air Optix plus HydraGlyde for Astigmatism (Iotrafalcon B) BUDI: 038065GMN000113GR	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Air Optix plus HydraGlyde Multifocal (Iotrafalcon B) BUDI: 038065GMN000115GV	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Air Optix Night & Day Aqua (Iotrafalcon A) BUDI: 038065GMN000116GX	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Air Optix Night & Day Aqua (Iotrafalcon A) BUDI: 038065GMN000117GZ	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Air Optix Colors (Iotrafalcon B)	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



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
BUDI: 038065GMN000129H8	<input checked="" type="checkbox"/> Class IIa	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: GRIESHABER® Advanced DSP Tips (PRO-072-STED) BUDI: 038065GMN000149HE	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: GRIESHABER® Advanced DSP Tips (PRO-072-STED) BUDI: 038065GMN000150GX	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Advanced Backflush Handles DSP (PRO- 120-STED) BUDI: 038065GMN000153H5	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Ophthalmic Hooks DSP (including sub-Families Spatulas and Pics DSP and FINESSE® Flex Loop DSP (PRO-125- STED) BUDI: 038065GMN000160H2	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Ophthalmic Diathermy Probes DSP (PRO-110- STED) BUDI: 038065GMN000155H9	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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
Device Name: GRIESHABER ULTRASHARP® Knives (PRO- 117-STED) BUDI: 038065GMN000159HH	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: GRIESHABER REVOLUTION® DSP Instruments (PRO-059- STED) BUDI: 038065GMN000160H2	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: 20 GA CURVED LASER PROBE BUDI: 038065GMN000178HM	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Laureate Vit Handpiece BUDI: 038065GMN000185HJ	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: 23GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1mm BUDI: 038065GMN000187HN	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: 20GA TOTALPLUS® Vit Pak-5000CPM BUDI: 038065GMN000188HQ	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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
Device Name: Constellation® Tray Arm Cover BUDI: 038065GMN000190HB	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: CENTURION System BUDI: 038065GMN000192HF	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Legion System BUDI: 038065GMN000192HF	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: LenSx Laser System BUDI: 038065GMN000207H3	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: LenSx Laser Patient Interface BUDI: 038065GMN000208H5	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	Individual Article number: <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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Precision1 (verofilcon A) BUDI: 038065GMN000218H8	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	Individual Article number: <input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: Precision1 for Astigmatism (verofilcon A) BUDI: 038065GMN000219HA	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: TOTAL30 (leofilcon A) BUDI: 038065GMN000223GZ	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: TOTAL30 for Astigmatism (leofilcon A) BUDI: 038065GMN000224H3	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES TOTAL1 (delefilcon A) BUDI: 038065GMN000104GQ	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES TOTAL1 PRO (delefilcon A) BUDI: 038065GMN000105GS	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES TOTAL1 Multifocal (delefilcon A)	<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: Certificate G1 020895 0393 Rev. 00



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
BUDI: 038065GMN000106GU		<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	TÜV SÜD Product Service GmbH
Device Name: DAILIES TOTAL1 PRO Multifocal (delefilcon A) BUDI: 038065GMN000107GW	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES TOTAL1 for ASTIGMATISM (delefilcon A) BUDI: 038065GMN000108GY	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES AquaComfort Plus (nelfilcon A) BUDI: 038065GMN000118H3	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES AquaComfort Plus Toric BUDI: 038065GMN000120GN	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES AquaComfort Plus Multifocal (nelfilcon A) BUDI: 038065GMN000121GQ	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Focus DAILIES (nelfilcon A)	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows:



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
BUDI: 038065GMN000122GS	<input checked="" type="checkbox"/> Class IIa	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: FreshLook One-Day (nelfilcon A) BUDI: 038065GMN000125GY	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: DAILIES FreshLook Illuminate (nelfilcon A) BUDI: 038065GMN000127H4	<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 Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: SMARTCataract Procedural Planner BUDI: 038065GMN000232H2	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input checked="" 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: PERFLUORON (purified perfluoron-octane) liquid FID 98156 KIT BUDI: 038065GMN000255HE	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Custom Pak – Is BUDI: 038065GMN000268HP	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH



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
Device Name: Custom Pak - IIa BUDI: 038065GMN000267HM	<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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Custom Pak - IIb BUDI: 038065GMN000258HL	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 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
NA	NA	NA	NA

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-13	713282895, 713307489, 713304919, 713307490	Initial issue