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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
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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.

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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

Francesco Bianchi (May 13, 2024 14:21 GMT+8)

Francesco Bianchi
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Polyana Vilela Heimes (May 13, 2024 10:46 GMT+2)

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**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **ProVisc Ophthalmic Viscosurgical Device** **BUDI:** **038065GMN000009GV**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **BSS Sterile Irrigating Solution** **BUDI:** **038065GMN000011GG**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **IOL WEB-BASED CALCULATORS** **BUDI:** **038065GMN000018GW**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☒ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Alcon Incisional Instruments and**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or	☒ 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**		☐ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: Alcon Compressed Cellulose Devices **BUDI: 038065GMN000035GW**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Alcon Cannulas and Cystitomes (needles)** **BUDI:** **038065GMN000043GV**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Alcon Cannulas and Cystitomes (opthalimic infusion/aspiration)** **BUDI:** **038065GMN000044GX**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Alcon Cannulas and Cystitomes (opthalimic infusion/aspiration)** **BUDI:** **038065GMN000046H3**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Alcon Cannulas and Cystitomes (opthalimic infusion/aspiration)** **BUDI:** **038065GMN000047H5**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **BSS Plus Sterile Irrigating Solution** **BUDI:** **038065GMN000052GW**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ 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
		Individual Article number:	
Device Name: **Monarch IOL Delivery System (Handpiece)** **BUDI:** **038065GMN000063H3**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Monarch IOL** **Delivery System (Cartridge)** **BUDI:** **038065GMN000064H5**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **CONSTELLATION TABLETOP** **BUDI:** **038065GMN000067HB**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Constellation Fragmentation Pak** **BUDI:** **038065GMN000072H4**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **UltraVit 20 GA, 5000 CPM** **BUDI:** **038065GMN000073H6**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **PurePoint Laser System** **BUDI:** **038065GMN000074H8**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or	☒ 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
	☐ Class I devices with measuring function	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: **PurePoint Laser Indirect Ophthalmoscope (LIO)** **BUDI:** **038065GMN000075HA**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Silicone I/A Tip, Bent** **BUDI:** **038065GMN000079HJ**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **SYSTANE Lubricant Eye Drops FID 102344** **BUDI:** **038065GMN000084HB**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **AOSEPT PLUS w/HydraGlyde FID 120947A**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A or	☒ 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**	☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	TÜV SÜD Product Service GmbH
Device Name: **Air Optix plus HydraGlyde (lotrafilcon B)** **BUDI:** **038065GMN000111GM**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Air Optix plus HydraGlyde for Astigmatism (lotrafilcon B)** **BUDI:** **038065GMN000113GR**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Air Optix plus HydraGlyde Multifocal (lotrafilcon B)** **BUDI:** **038065GMN000115GV**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Air Optix Night & Day Aqua (lotrafilcon A)** **BUDI:** **038065GMN000116GX**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Air Optix Night & Day Aqua (lotrafilcon A)** **BUDI:** **038065GMN000117GZ**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Air Optix Colors (lotrafilcon B)**	☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ 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**	☒ Class IIa	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: **GRIESHABER®** **Advanced DSP Tips (PRO-072-STED)** **BUDI:** **038065GMN000149HE**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **20 GA CURVED LASER PROBE** **BUDI:** **038065GMN000178HM**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Laureate Vit Handpiece** **BUDI:** **038065GMN000185HJ**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **20GA TOTALPLUS® Vit Pak-5000CPM** **BUDI:** **038065GMN000188HQ**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ 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
		Individual Article number:	
Device Name: **Constellation® Tray Arm Cover** **BUDI:** **038065GMN000190HB**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **CENTURION System** **BUDI:** **038065GMN000192HF**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Legion System** **BUDI:** **038065GMN000192HF**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **LenSx Laser System** **BUDI:** **038065GMN000207H3**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **LenSx Laser Patient Interface** **BUDI:** **038065GMN000208H5**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Precision1 (verofilcon A)** **BUDI:** **038065GMN000218H8**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or	☒ 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
		☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	
Device Name: **Precision1 for Astigmatism (verofilcon A)** **BUDI:** **038065GMN000219HA**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **TOTAL30 (lehfilcon A)** **BUDI:** **038065GMN000223GZ**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **TOTAL30 for Astigmatism (lehfilcon A)** **BUDI:** **038065GMN000224H3**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES TOTAL1 (delefilcon A)** **BUDI:** **038065GMN000104GQ**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES TOTAL1 PRO (delefilcon A)** **BUDI:** **038065GMN000105GS**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES TOTAL1 Multifocal (delefilcon A)**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or	☒ 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**		☐ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES TOTAL1 for ASTIGMATISM (delefilcon A)** **BUDI:** **038065GMN000108GY**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES AquaComfort Plus (nelfilcon A)** **BUDI:** **038065GMN000118H3**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES AquaComfort Plus Toric** **BUDI:** **038065GMN000120GN**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES AquaComfort Plus Multifocal (nelfilcon A)** **BUDI:** **038065GMN000121GQ**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Focus DAILIES (nelfilcon A)**	☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ 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**	☒ Class IIa	or ☐ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **DAILIES FreshLook Illuminate (nelfilcon A)** **BUDI:** **038065GMN000127H4**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **SMARTCataract Procedural Planner** **BUDI:** **038065GMN000232H2**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☒ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **PERFLUORON (purified perfluoro-n-octane) liquid FID 98156 KIT** **BUDI:** **038065GMN000255HE**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Custom Pak – Is** **BUDI:** **038065GMN000268HP**	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 020895 0393 Rev. 00 TÜV SÜD Product Service GmbH
Device Name: **Custom Pak - IIb** **BUDI:** **038065GMN000258HL**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ 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