Notified Body Confirmation Letter Reference: C611227

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Contacare Ophthalmics & Diagnostics

310/B&E, Dabhasa Village, Padra Taluka, Vadodara District-391440, Gujarat, India

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or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

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

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

Place and date:
Høvik, 2023/05/15

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Luis André Lourenco Fernandes
Management Representative

Table 1: Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sodium Hyaluronate Ophthalmic Solution (HILURON) Brand – Hiluron Variants: HILURON 1% PFS, HILURON 1.4% PFS & HILURON 3% PFS 89041214000NAHA00RG	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Hydroxypropyl Methylcellulose Ophthalmic Viscosurgical Solution 2% & 2.4% (Viscolon) Brand: Viscolon Variants: • Viscolon 2% 2 mL PFS with 23G canulla • Viscolon 2% 3 mL PFS with 23G canulla and • Viscolon 2% 5 mL glass vials with 23G canulla Viscolon 2.4% 2 mL PFS with 23G canulla 89041214000HPMC00VL	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Balanced Salt Solution (Sterile Irrigating Solution) Brand: Contasol Plus 890412140000BSS00K9	Class III	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Balanced Salt Solution (Sterile Irrigating Solution) Brand: • Contasol • Contasol -H	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
890412140000BSS00K9			
Trypan blue Solution 0.06% BlueRhexis Vista blue 8904121400000TB00AY	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
GONIOVISC (Hydroxypropyl Methylcellulose Ophthalmic Solution) 2% & 2.5% Goniovisc 2% Goniovisc 2.5% 8904121400000GV00B9	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Silicon Oil (CONTASIL) Brand : Contasil Variants: Contasil 1000 Contasil 5000 8904121400000SO00CS	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Contacare Multipurpose Solution (Contacare MPS, MPDS, RGP sparkle, Moist Drops) Contacare MPS, Contacare MPDS, Contcare RGP SPARKLE, MOIST DROP 89041214000CCMS00RL	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Fluorescein Sodium Ophthalmic Strips USP FluoStrip, Fluorets, Optistrip-FL, I-Fluoro- 1 mg, I-Glo, I-Glo Plus HiGlo, HospiFluo Strips 89041214000FSOS00YR	Class IIb	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB: 2460; Expiry date: 19 APR 2023
Tear Strips (Schirmer Tear Test Strips)	Class Is and Class M	n/a	Certificate number: #240391-2017-CE-IND-NA-PS 2.0; NB number NB:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tear Strip Spectrum schrimer 8904121400000TS00DM			2460; Expiry date: 19 APR 2023

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/15	C611227	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe