



**Notified Body Confirmation Letter Reference: C612229**

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:

**BIO-TECH VISION CARE PVT. LTD.**

- 1) Plot No. 555-556-557, Opp. Subham Tex-O-Pack, Khatraj-Vadsar Road, P.O.: Khatraj, Taluka, Kalol, Dist. Gandhinagar, Gujarat, India
- 2) Plot No. 4, PHARMEZ, Sarkhej-Bavla N.H. 8A, Village: Matoda, Taluka: Sanand, Dist.: Ahmedabad- 382213, Gujarat, India

**SRN Number: IN-MF-000008482**

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or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, 2023.05.16



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

**Menaka Singh**  
Management Representative

**Table 1: Devices covered by this letter:**

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	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
<p>Hydroxy Propyl Methyl Cellulose Ophthalmic Solutions USP 2% w/v and 2.4% w/v</p> <p>Basic UDI-DI: 890609220OVDQ9</p> <ul style="list-style-type: none"> <li>• Eye Visc PFS (2ml PFS and Pack of 10 PFS)</li> <li>• Metilon 20 PFS (2ml)</li> <li>• Eye Visc plus PFS (2ml)</li> <li>• Eye Visc PFS 2.4% (2ml PFS)</li> <li>• Opticel PFS (2ml PFS and Pack of 10 PFS)</li> </ul>	Class IIb	N/A	<p>Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0</p> <p>NB number NB:2460</p> <p>Expiry date: 18 May 2023</p>
<p>Sodium Hyaluronate Ophthalmic Solutions/</p> <p>Basic UDI-DI: 890609220OVDQ9</p> <ul style="list-style-type: none"> <li>• Bio-Hyalur (10 mg/ml) (1.0 ml, 1.6 ml PFS)</li> <li>• Bio-Hyalur Plus (14 mg/ml) (1.0 ml, 1.6 ml PFS)</li> <li>• Bio-Hyalur EV (18 mg/ml) (1.0 ml, 1.6 ml PFS)</li> <li>• Bio-Hyalur HV (24 mg/ml) (1.0 ml, 1.6ml PFS)</li> <li>• Bio-Hyalur SV (30 mg/ml) (1.0 ml, 1.6 ml PFS)</li> <li>• Bio-Hyalur DUO (1 ml PFS)</li> <li>• Viscotech 1% (10 mg/ml) (1 ml PFS)</li> </ul>	Class IIb	N/A	<p>Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0</p> <p>NB number NB:2460</p> <p>Expiry date: 18 May 2023</p>
<p>Trypan blue Ophthalmic solution/</p> <p>Basic UDI-DI: 890609220OSYE</p> <ul style="list-style-type: none"> <li>• Bio-Blue (1 ml PFS and Pack of 5 or 10 PFS)</li> <li>• Bio-Blue Plus (1 ml PFS and Pack of 5 or 10 PFS)</li> </ul>	Class IIb	N/A	<p>Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0</p> <p>NB number NB:2460</p> <p>Expiry date: 18 May 2023</p>
<p>Brilliant Blue G or Acid Blue 90 Ophthalmic Solution/</p> <p>Basic UDI-DI: 890609220OSYE</p> <ul style="list-style-type: none"> <li>• Bio Blue 90 (0.5 ml and 1 ml PFS)</li> <li>• Bio Blue 90 Plus (0.5 ml and 1 ml PFS)</li> </ul>	Class IIb	N/A	<p>Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0</p> <p>NB number NB:2460</p> <p>Expiry date: 18 May 2023</p>
<p>Combination of Brilliant Blue G or Acid Blue 90 and Trypan Blue</p>	Class IIb	N/A	<p>Certificate number: 277565-2018-CE-IND-NA-PS Rev.</p>

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	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
Ophthalmic Solution/ Basic UDI-DI: 890609220OSYE  • Bio Blue Duo (0.5 ml and 1 ml PFS)			2.0 NB number NB:2460 Expiry date: 18 May 2023
Silicone Oil 1000cst/ 5000 cst Basic UDI-DI: 890609220OEXJ • BIOSIL (10 ml PFS) • BIOSIL-F (10 ml PFS)	Class IIb	N/A	Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0 NB number NB:2460 Expiry date: 18 May 2023
Perfluoro-n-octane liquid Basic UDI-DI: 890609220OEXJ  • BIO OCTANE (5 ml & 7ml PFS)	Class IIa	N/A	Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0 NB number NB:2460 Expiry date: 18 May 2023
Perfluoro decalin liquid Basic UDI-DI: 890609220OEXJ  • BIO DECALIN (5 ml & 7ml PFS)	Class IIa	N/A	Certificate number: 277565-2018-CE-IND-NA-PS Rev. 2.0 NB number NB:2460 Expiry date: 18 May 2023

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/16	C612229	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