Notified Body Confirmation Letter Reference: C682785

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic 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:

ArcRoyal
Virginia Road
Kells, Co. Meath
A82 R862
Ireland

SRN Number: IE-MF-000004441

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 03.05.2024

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

Menaka Singh
Management Representative

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 120.3c 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)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
12-004948 Manifold 2-port 250 psi RH RA ON / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004951 Manifold 2-port 250 psi RH RA OFF / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004952 Manifold 3-port 250 psi RH RA OFF / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000249 Control Syringe 10 mL, Male, Luer Lock with thumb & finger rings / 539153604DC34671UW	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000304 Control Syringe 10 mL, Male, Rotating Adaptor with thumb & finger rings / 539153604DC34671UW	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000210 Pressure Monitoring Line, Male/Female, 150 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000235 Pressure Monitoring Line, Male/Female, 15 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000236 Pressure	Class IIa	N/A	10000370555-PA-NA-

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Monitoring Line, Male/Female, 120 cm / 5369153604DC34669VB			DNK DNV Product Assurance AS and 2460
12-000836 Pressure Monitoring Line, Male/Female, 30 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001776 Pressure Monitoring Line, Male/Female, 90 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000237 Injector Line 1200 psi 75 cm Luer Lock / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000608 Injector Line 1200 psi 120 cm Luer Lock / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000813 Injector Line 1200 psi 25 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001733 Injector Line 1200 psi 75 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001734 Injector Line 1200 psi 120 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001736 Braided High Pressure Line, fixed, female, rotating adaptor, 48” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001737 Braided High Pressure Line, fixed, female, rotating adaptor, 30” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001738 Braided High Pressure Line, fixed, female, rotating adaptor, 20” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001740 Braided High Pressure Line, fixed, female with wing 48” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001741 Braided High Pressure Line, fixed, female with wing 30” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
12-001743 Braided High Pressure Line, fixed, female with wing 10" / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001771 Injector Line 1200 psi 50 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001915 PTCA Accessory Kit / 539153604DC34692V6	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001855 Y-Connector, single / 539153604DC34690V2	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001856 Y-Connector, double / 539153604DC34690V2	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001624 Torque device / 539153604DC34691V4	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-003846 Admin Set AAA / 539153604DC34693V8	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004925 Coronary Guidewire Introducer Needle 19ga x 38 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004924 Coronary Guidewire Introducer Needle 21ga x 38 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004943 Coronary Guidewire Introducer Needle 18ga x 77 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-002069 Coronary Guidewire Introducer Needle 18 ga x 70 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-LHCB01 Light Handle Cover 1/pkt S / 539153604DC34688VF	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-LHCB02 Light Handle Cover 2/pkt S / 539153604DC34688VF	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-26001 Skin Marker Std	Class IIa	N/A	10000370555-PA-NA-

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tip / 539153604DC34684V7			DNK DNV Product Assurance AS and 2460
AR-26002 Skin Marker Fine Tip / 539153604DC34684V7	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-32200 Cautery Tip Cleaner / 539153604DC34687VD	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-003704 Inflation device / 539153604DC34683V5	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
Procedure Packs	N/A	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460 (*Procedure packs according to article 12, section 3)

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/25	C682785	Initial issue
2024/05/03	C682785	Addition of procedure packs

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.