Notified Body Confirmation Letter Reference: C687979

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:

DeRoyal Industries Inc.

200 DeBusk Lane

Powell, Tennessee 37849

USA

SRN Number US-MF-000002102

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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, 2024/06/28

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

André Fernandes
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
Neonatal Skin Temperature Probes 07497560037N38V	IIb	Temperature Probes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Adult Skin Temperature Probes 07497560037R28V	IIb	Temperature Probes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
General Purpose Temperature Probes and Nasopharyngeal Temperature Probes 07497560037R48V	IIb	Temperature Probes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Tympanic Temperature Probes 07497560037R98V	IIb	Temperature Probes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Foley Catheters with Temperature Probes 07497560017R78R	IIb	Temperature Probes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Esophageal Stethoscopes 07497560027R58T	IIb	Esophageal Stethoscope with Temperature Sensor (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 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
Esmark Bandages 07497560194D39C	Is	N/A	Certificate No.: 10000408810-PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460AS, Notified Body nr:2460
Light Handle Covers 07497560184BM9A	Is	Equipment Covers (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Rigid Light Handle Covers 07497560184BR9A	Is	Equipment Covers (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Surgical Skin Markers 07497560264B299	Is	Surgical Markers (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Negative Pressure Wound Therapy Dressing Kits 07497561595NP9V	IIb	Transeal Transparent Film, Black Foam, and Top Draw connector (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Angio Manifolds and Stopcocks 07497560487C29K	IIa	Angio Manifolds Angio Stopcocks (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Angio Control Syringes 07497560487C39K	IIa	Control Syringes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Instrument Pads 07497560064B393	Is	NA	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Tube/Cord Holders 07497560064B993	Is	Instrument Holder (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Sharp Stop Transfer Tray 07497560234BD93	Is	Instrument Holder (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Standard Stockinettes 07497560274D19B	Is	Stockinettes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Impervious Stockinettes 07497560274D29B	Is	Stockinettes (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Eye Spear Fine Dissectors 07497560144AF92	IIa	Surgical Sponges (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Laparoscopic Dissectors 07497560144G892	IIa	Surgical Sponges (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 2460
Dissecting Sponges	IIa	Surgical Sponges (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified

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
07497560144AC92			Body nr: 24602460
Specialty Sponges 07497560144AH92	IIa	Surgical Sponges (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Cotton Balls 07497560144AB92	IIa	Surgical Sponges (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Defogger Antifog Solution 07497560154G194	IIa	Anti-fog Solutions (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Suture Boots 07497560294BY9F	IIa	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Suture Boots Non-Sterile 07497560214GN8X	IIa	Protectors for Surgical Forceps (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Insufflation Tubing 07497560214G28X	IIa	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Electrosurgical Electrodes Non-Sterile 07497560177EN98	IIb	Electrosurgical Pencils and Blades (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Electrosurgical Pencils 07497560177E198	IIb	Electrosurgical Pencils and Blades (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Electrodes 07497560177E398	IIb	Electrosurgical Pencils and Blades (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Cautery Tip Cleaner 07497561584B19T	Is	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Holsters 07497560067E193	Is	Instrument Holder (Name change only)	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Bipolar Cords 07497561587E19T	Is	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Multidex Powder 07497560115AC8P	IIb	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 24602460
Multidex Gel 07497560115AC8G	IIb	N/A	Certificate No.: 10000408810- PA-NA-DNK DNV Product Assurance AS, Notified Body nr: 246024602460

Table 2: Devices covered by this letter and for which the NB is NOT 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			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/24	C687979	Initial issue
2024/06/28	C687979	To correctly identify the correct certificate number. Adding the device “Negative Pressure Wound Therapy Dressing Kits”

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.