



Notified Body Confirmation Letter Reference: C625217

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:

BK Medical ApS
Mileparken 34
2730 Herlev
Denmark

SRN Number: DK-MF-000006447

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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, 2024/02/15



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

André Fernandes
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this letter invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

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
GMN 570491600601B4 / I12C5b / 9024	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600602B6 / X12C4 / 9026	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600601B4 / I12C5 / 9034	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600603B8 / I13C3f / 9076	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600602B6 / Rob12C4 / 9096	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-use Needle Guide / UA1337	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600601B4 / I14C5I / 9015	IIa	N/A	10000463963-PA- NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN	IIa	N/A	10000463963-PA-

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
570491600601B4 / I14C5T / 9016			NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-use Needle Guide / UA1336	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600403AW / E14CL4b / 9048	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600403AW / E11C3b / 9008	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600403AW / E14C4t / 9018	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600401AS / E10C4 / 9019	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600401AS / E13C2 / 9029	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600404AY / X14L4 / 9038	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600404AY / 20R3 / 9052	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601301AU / Dummy Channel Bracket / UA1325-W	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601001AD / Reusable End-Fire Needle Guide / UA1282	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Reusable needle guide (UA1282)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601001AD / Reusable Side-Fire Needle Guide / UA1326	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Reusable biplane biopsy guide (UA1326)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601001AD / Reusable Dual Needle	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance

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
Guide / UA1328		named Reusable dual biopsy guide (UA1328)	AS / 2460
GMN 570491601001AD / Reusable End-Fire Needle Guide / UA1349	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Reusable needle guide (UA1349)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-use biplane biopsy guide / UA1322-S	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-Use 14G biplane biopsy guide UA1322-S14	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-Use End-Fire Needle Guide / UA1323-S	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Single-use endfire biopsy guide (UA1323-S)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-Use Dual Needle Guide / UA1329-S	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Single-use dual biopsy guide (UA1329-S)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-Use End-Fire Needle Guide / UA1339	IIa	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev. 0 this device is named Single-use needle guide (UA1339)	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600503B3 / 9C2 / 9002	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600502AZ / 13L4w / 9011	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600502AZ / 14L3 / 9051	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600502AZ / 18L5 / 9070	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN	IIa	N/A	10000463963-PA-

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
570491600502AZ / 18L5s / 9081			NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601101AJ / Single Use Needle Guide / UA1338	I (s)	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
570491600301AM / X18L5s / 9009	III	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460 10000463966-PA-NoMA-DNK Rev 0.0. DNV Product Assurance AS / 2460
570491600201AG / N13C5 / 9062	III	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460 10000463968-PA-NoMA-DNK Rev. 0.0/ DNV Product Assurance AS / 2460
570491600201AG / N11C5s / 9063	III	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460 10000463968-PA-NoMA-DNK Rev. 0.0/ DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-use needle guide / UA1345	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601102AL / Single-use needle guide / UA1346	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
(GMN) 570491600501AX / 5P1e / 9087	IIb	In the Appendix Rev. 2 to 10000463963-PA-NoMA-DNK Rev.0 5P1e / 9087 is classified as a IIa under 93/42/EEC	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
570491600101AB /	IIb	N/A	10000463963-PA-

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
bkSpecto Ultrasound System / 1300			NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
570491600101AB / 2300 Ultrasound System / 2300 bk3000/bk5000/bkActiv	IIb	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600503B3 / 6C2 / 9040	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600503B3 / 5C1e / 9085	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600502AZ / 14L3e / 9086	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491600502AZ / 8L2 / 9032	IIa	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460
GMN 570491601101AJ / Single Use Needle Guide / UA1344	I (s)	N/A	10000463963-PA-NoMA-DNK Rev 0.0 / DNV Product Assurance AS / 2460

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
NA			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/08/15	C625217	Initial issue
2024/01/17	C625217	Rev. 1: <ul style="list-style-type: none"> Reference to MDD certificate 10000463968-PA-NoMA-DNK Rev. 0.0/ DNV Product Assurance AS / 2460 has been added for class III devices 9009, 9062, and 9063 The configurations for device 2300 Ultrasound System have been added Device name for UA1322-S and UA1322-S14 has been corrected
2024/02/15	C625217	Rev. 2: <ul style="list-style-type: none"> Device 9009 missing Reference to certificate 10000463966-PA-NoMA-DNK Rev 0.0. - 20210520 – 1621543920520. This has now been added

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.