



Notified Body Confirmation Letter Reference: C684211

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:

GENORAY Co., Ltd

60, Dunchon-daero 541beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13212, Republic of Korea

SRN Number (if available): KR-MF-000021014

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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.

Place and date:
Høvik, 2024/05/30



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

Rajesh Kumar Chellappan
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

- 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
ZEN-2090 Turbo (ZEN-CX2090, ZEN-2090 Pro, XENO-360) / 880924406ZEN2090QJ	IIb	MDD legacy device: ZEN-2090 Pro (ZEN-CX2090, ZEN-2090 Turbo, XENO-360) (only model name change)	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
OSCAR (OSCAR Prime) / 880924406OSCARPRIMERS	IIb	N/A	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
OSCAR (OSCAR Classic (Unique Class)) / 880924406OSCARCLASSICEZ	IIb	N/A	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
GIX-1 / 880924406GIX1K2	IIa	MDD legacy device: PortView (GIX-1) (only model name change)	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
OSCAR 15FD (Unique FD) OSCAR 15i, OSCAR 15iL / 880924406OSCAR15UD	IIb	MDD legacy device: OSCAR 15 (Unique FD)	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
PAPAYA (GDP-1), PAPAYA Plus (GDP-1C, VOLUX 29) / 0880924406PAPAYALH	IIb	N/A	- Certificate Number: 10001-2017-CE-KOR-NA-PS Rev. 9.0 -NB Identification:

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
			DNV Product Assurance AS (2460)
PAPAYA 3D, PAPAYA 3D Plus (VOLUX 55), PAPAYA 3D Premium, PAPAYA 3D Premium Plus / 880924406PAPAYA3D6T	IIb	N/A	- Certificate Number: 10001-2017-CE- KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
DVAS (DVAS-C, DVAS-W, DVAS-M) / 880924406DVASLB	IIb	N/A	- Certificate Number: 10001-2017-CE- KOR-NA-PS Rev. 9.0 -NB Identification: DNV Product Assurance AS (2460)
PORT-X IV (ZEN-PX4), PORT-X IVe (ZEN-PX4e) / 880924406PORTXIV9S	IIb	N/A	- Certificate Number: 10001-2017-CE- KOR-NA-PS Rev. 9.0 -NB Identification: 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/30	C684211	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.