Notified Body Confirmation Letter Reference: C719747

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:

Oro Clean Chemie AG
Allmendstrasse 21
8320 Fehraltorf
Switzerland

SRN Number (if available): NA

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

Place and date:
Høvik, 2024/10/02

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

C. Rajesh Kumar

Rajesh Kumar Chellappan
Management Representative

- 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
Surface disinfectant - CLEANSEPT® 22+ 955100144OF100011SWBK 955100144OF100012SWBQ	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Light 955100144OF100010SLAQ	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Maxx 955100144OF100007SLBL	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Omni 955100144OF100005SLBA	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Omni Wipes 955100144OF100005SWBY	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Opti 955100144OF100006SLBF	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Sensitive 955100144OF100021SLB4	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Sensitive Wipes 955100144OF100021SWBS	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Wipes 955100144OF100013SWBV 955100144OF100011SWBK	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - DENTIRO® Zero 955100144OF100020SLAX	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 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
Surface disinfectant - ISORAPID® OP-Forte AF 955100144OF100001SLAN	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - ISORAPID® Spray 955100144OF100022SLB9	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - OROLIN® Burbath 955100144OF100003ILA2	Class IIb	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - OROLIN® Multisept 955100144OF100009ILAY	Class IIb	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - OROLIN® Multisept Plus 955100144OF100008ILAT	Class IIb	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - ASEPTOPRINT® Liquid 955100144OF100016AL9Y	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - ASEPTOPRINT® Spray 955100144OF100021AL9E	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460
Aspirating unit disinfectant - ORO CLEAN® Plus 955100144OF100014AL9N	Class IIa	NA	10000400154-PA-NA-MYS, rev.1; NB 2460

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/10/02	C719747	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.