

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 10000400154-PA-NA-MYS, rev.1

Project No.: PRJN-195868-2020-PA-MYS

Valid Until: 27 May 2024

This is to certify that the quality system of:

Oro Clean Chemie AG

Allmendstrasse 21, 8320 Fehraltorf, Switzerland

For design, production and final product inspection/testing of:

**DISINFECTANTS, CLEANERS, DECONTAMINATION AGENTS FOR
INVASIVE AND NON-INVASIVE MEDICAL DEVICES**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 30 March 2021



For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Mariann Jeremiassen
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	10 November 2020
1.0	Scope reduction and Products addition within MDD IA assessment (in Bold)	01 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Surface Disinfectants	CLEANSEPT® 22+ DENTIRO® Jumbo Wipes DENTIRO® Light DENTIRO® Maxx DENTIRO® Omni DENTIRO® Omni Wipes DENTIRO® Opti DENTIRO® Sensitive DENTIRO® Sensitive Wipes DENTIRO® Wipes DENTIRO® Zero ISORAPID® OP-Forte AF ISORAPID® Spray	IIa
Surgical Instrument Disinfectants	OROLIN® Burbath OROLIN® Multisept OROLIN® Multisept Plus	IIb
Dental Impression Disinfectants	ASEPTOPRINT® Liquid ASEPTOPRINT® Spray	IIa
Aspirating Unit Disinfectant	ORO CLEAN® Plus	IIa

The complete list of devices is filed with the Notified Body



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

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 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.

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market

Manufacturer name	Oro Clean Chemie AG
Manufacturer address and contact details	Allmendstrasse 21 8320 Fehraltorf Switzerland info@oroclean.com
Single Registration Number (SRN) (if available)	

Authorised Representative name (if applicable)	Oro Clean Chemie s.r.o.
Authorised Representative address and contact details	Vinohradská 2828/151 Žižkov, 130 00 Praha 3 Czech Republic info@oroclean.cz
Single Registration Number (SRN) (if available)	CZ-AR-000035935

Notified body name (if applicable)	DNV Product Assurance AS ☒ See attached schedule
Notified body number (if applicable)	2460 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	10000400154-PA-NA-MYS, rev.1 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27 May 2024 ☒ See attached schedule

End date of extended validity/transition period	31 December 2028 ☒ See attached schedule
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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
 - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
 - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.
- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made/submitted by us to a notified body no later

than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- ☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Oro Clean Chemie AG

Location & Date: Fehraltorf, 10.05.2024

Signature, Print Name, Title:

Lee Moi Wong
Chief Research Officer
Fehraltorf

Lee Moi Wong
2024.05.10
11:20:24 +02'00'

Contact Details (at least email): leemoi.wong@oroclean.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
CLEANSEPT® 22+	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Jumbo Wipes	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Light	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Maxx	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Omni	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Omni Wipes	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Opti	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Sensitive	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Sensitive Wipes	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
DENTIRO® Wipes	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	

DENTIRO® Zero	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
ISORAPID® OP- Forte AF	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
ISORAPID® Spray	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
OROLIN® Burbath	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
OROLIN® Multisept	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
OROLIN® Multisept Plus	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
ASEPTOPRINT® Liquid	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
ASEPTOPRINT® Spray	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
ORO CLEAN® Plus	10000400154-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	