

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000400159-PA-NA-MYS, rev.1

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
United Disinfectant Manufacturers AG

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

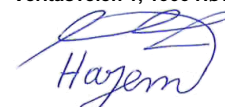
A device already covered by the certification is placed on the market under an additional name or Identifier.

Products covered by this Certificate (replaces information on certificate): 10000400159-PA-NA-MYS, rev.1 and according to the approved technical documentation in 2020 only.		
Product Description	Product Name	Class
Surface Disinfectants	actisolve® alcofree actisolve® alcolite actisolve® alcolite wipes actisolve® alcoplus actisolve® alcoplus wipes actisolve® alcopro actisolve® alcopro wipes actisolve® alcoquats actisolve® alcoquats wipes actisolve® alcosept actisolve® alcospray actisolve® alcowipes actisolve® maxsurface bepro disinfectant concentrate bepro disinfectant spray bepro disinfectant wipes	Ila

Place and date:
Høvik, 15 March 2023



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



Hazem Tinawi
Technical Reviewer

	bepro sensitive spray PROSEPT® Activa PROSEPT® Activa Wipes PROSEPT® Blaze PROSEPT® Blaze Wipes PROSEPT® Floor PROSEPT® Sensi PROSEPT® Spray PROSEPT® Swipes PROSEPT® Ultima PROSEPT® Ultima Wipes PROSEPT® Wipes	
Surgical Instrument Disinfectants	actisolve® instrusafe actisolve® instrusafe eco actisolve® rotasafe bepro disinfectant I bepro disinfectant R PROSEPT® Burs PROSEPT® Fortis PROSEPT® Instru	IIb
Dental Impression Disinfectants	actisolve® impresoak actisolve® imprespray Cavex ImpreSafe PROSEPT® Impression S	Ila
Aspirating Unit Disinfectant	actisolve® aspisept PROSEPT® Jet D	Ila

Appendix History -		
Revision	Description	Issued Date
0	<p>A new EU representative, replacing the one stated on the certificate, has been accepted (EU Representative has been changed from Oro Clean Chemie s.r.o. to United Disinfectant Manufacturers AG.)</p> <p>The legal name of a site has changed. (Change of manufacturer's name from Oro Clean Chemie (Schweiz) AG to United Disinfectant Manufacturers AG.</p> <p>The name or identifier of a device already covered by the certification, has been revised. (actisolve[®] scopysafe brand has been removed.)</p> <p>A device already covered by the certification is placed on the market under an additional name or Identifier. (Addition of Cavex ImpreSafe as additional brand name for actisolve[®] impresoak</p>	18 December 2022
1	<p>A device already covered by the certification is placed on the market under an additional name or Identifier.</p> <p>(1. Addition of PROSEPT[®] Floor and bepro disinfectant concentrate as additional brand names for actisolve[®] maxsurface;</p> <p>2. Addition of PROSEPT[®] Sensi and bepro sensitive spray as additional brand names for actisolve[®] alcofree;</p> <p>3. Addition of PROSEP[®] Ultima as additional brand name for actisolve[®] alcolite;</p> <p>4. Addition of PROSEPT[®] Activa as additional brand name for actisolve[®] alcopro;</p> <p>5. Addition of PROSEPT[®] Blaze as additional brand name for actisolve[®] alcoplus;</p> <p>6. Addition of PROSEPT[®] Spray and bepro disinfectant spray as additional brand names for actisolve[®] alcoquats;</p> <p>7. Addition of PROSEPT[®] Wipes and bepro disinfectant wipes as additional brand names for actisolve[®] alcowipes;</p> <p>8. Addition of PROSEPT[®] Activa Wipes as additional brand name for actisolve[®] alcopro wipes;</p> <p>9. Addition of PROSEPT[®] Blaze Wipes as additional brand name for actisolve[®] alcoplus wipes;</p> <p>10. Addition of PROSEPT[®] Swipes as additional brand name for actisolve[®] alcoquats wipes;</p> <p>11. Addition of PROSEPT[®] Ultima Wipes as additional brand name for actisolve[®] alcolite wipes;</p> <p>12. Addition of PROSEPT[®] Fortis and bepro disinfectant I as additional brand names for actisolve[®] instrusafe;</p> <p>13. Addition of PROSEPT[®] Burs and bepro disinfectant R as additional brand names for actisolve[®] rotasafe;</p> <p>14. Addition of PROSEPT[®] Instru as additional brand name for actisolve[®] instrusafe eco;</p> <p>15. Addition of PROSEPT[®] Jet D and as additional brand name for actisolve[®] aspisept; and</p> <p>16. Addition of PROSEPT[®] Impression S as additional brand name for actisolve[®] imprespray.) (in Bold)</p>	13 March 2023

DECLARATION OF CHANGE OF LEGAL MANUFACTURER

Fehraltorf, 13 November 2024


Subject: Declaration of Legal Manufacturer Change from Hygiene360 AG to United Disinfectant Manufacturers AG

To whom it may concern,

We hereby formally declare a change in the legal manufacturer for our products from Hygiene360 AG to United Disinfectant Manufacturers AG, effective 15 March 2023.

The new legal manufacturer, United Disinfectant Manufacturers AG operates under a quality management system certified to the same scope as Hygiene360 AG, 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.

Yours sincerely

 Lee Moi Wong
2024.11.13
10:51:23
+01'00'

Lee Moi Wong
Chief Research Officer



Notified Body Confirmation Letter Reference: C703693

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:

United Disinfectant Manufacturers 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.

Place and date:
Høvik, 18.11.2024



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

Menaka Singh
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
Surface disinfectant - actisolve® alcofree 955100187OF100020SLJG	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcolite 955100187OF100005SLJT	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcolite wipes 955100187OF100005SWKH	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcoplus 955100187OF100007SLK5	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcoplus wipes 955100187OF100007SWKT	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcopro 955100187OF100006SLJY	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcopro wipes 955100187OF100006SWKN 955100187OF100031SWKJ	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcoquats 955100187OF100021SLJM 955100187OF100022SLJS	Class IIa	NA	10000400159-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 - actisolve® alcoquats wipes 955100187OF100021SWKB	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcosept 955100187OF100023SLJX	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcospray 955100187OF100010SLJ9	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® alcowipes 955100187OF100013SWKE 955100187OF100011SWK4 955100187OF100012SWK9	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - actisolve® maxsurface 955100187OF100001SLJ7	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - bepro disinfectant concentrate 955100187OF100001SLJ7	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - bepro disinfectant spray 955100187OF100021SLJM	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - bepro disinfectant wipes 955100187OF100011SWK4	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - bepro sensitive spray 955100187OF100020SLJG	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Activa 955100187OF100006SLJY	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Activa Wipes 955100187OF100006SWKN 955100187OF100031SWKJ	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Blaze 955100187OF100007SLK5	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Blaze Wipes 955100187OF100007SWKT	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Floor 955100187OF100001SLJ7	Class IIa	NA	10000400159-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 - PROSEPT® Sensi 955100187OF100020SLJG	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Spray 955100187OF100021SLJM	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Swipes 955100187OF100021SWKB	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Ultima 955100187OF100005SLJT	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Ultima Wipes 955100187OF100005SWKH	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surface disinfectant - PROSEPT® Wipes 955100187OF100012SWK9 955100187OF100011SWK4	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - actisolve® instrusafe 955100187OF100008ILJC	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - actisolve® instrusafe eco 955100187OF100009ILJH	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - actisolve® rotasafe 955100187OF100003ILHK	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - bepro disinfectant I 955100187OF100008ILJC	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - bepro disinfectant R 955100187OF100003ILHK	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - PROSEPT® Burs 955100187OF100003ILHK	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-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
Surgical instrument disinfectant - PROSEPT® Fortis 955100187OF100008ILJC	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Surgical instrument disinfectant - PROSEPT® Instru 955100187OF100009ILJH	Class IIb excluding Class IIb implantable non-WET	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - actisolve® impresoak 955100187OF100018ALHT 955100187OF100016ALHH	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - actisolve® imprespray 955100187OF100021ALGX	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - Cavex ImpreSafe 955100187OF100018ALHT	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Dental impression disinfectant - PROSEPT® Impression S 955100187OF100021ALGX	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Aspirating unit disinfectant - actisolve® aspisept 955100187OF100014ALH7	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 2460
Aspirating unit disinfectant - PROSEPT® Jet D 955100187OF100014ALH7	Class IIa	NA	10000400159-PA-NA-MYS, rev.1; NB 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	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/11/18	C703693	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.