

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	IIa
Aspirating Unit Disinfectant	actisolve® aspisept PROSEPT® Jet D	IIa

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