

## 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	United Disinfectant Manufacturers AG
Manufacturer address and contact details	Allmendstrasse 21 8320 Fehraltorf Switzerland <a href="mailto:info@udm.swiss">info@udm.swiss</a>
Single Registration Number (SRN) (if available)	

Authorised Representative name (if applicable)	United Disinfectant Manufacturers AG
Authorised Representative address and contact details	Dr. Grass-Strasse 12 9490 Vaduz Principality of Liechtenstein <a href="mailto:info@udm.li">info@udm.li</a>
Single Registration Number (SRN) (if available)	LI-AR-000036155

Notified body name (if applicable)	DNV Product Assurance AS <input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	2460 <input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	10000400159-PA-NA-MYS, rev.1 <input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27 May 2024 <input checked="" type="checkbox"/> See attached schedule

End date of extended validity/transition period	31 December 2028 <input checked="" type="checkbox"/> 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: United Disinfectant Manufacturers AG

Location & Date: Fehraltorf, 10.05.2024

Signature, Print Name, Title:

Lee Moi Wong  
Chief Research Officer  
Fehraltorf

Lee Moi Wong  
2024.05.10  
11:23:01  
+02'00'

Contact Details (at least email): [leemoi.wong@udm.swiss](mailto:leemoi.wong@udm.swiss)

## 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)
actisolve® alcofree	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcolite	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcolite wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcoplus	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcoplus wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcopro	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcopro wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcoquats	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcoquats wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcosept	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	

actisolve® alcospray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® alcowipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® maxsurface	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant concentrate	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant spray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro sensitive spray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Activa	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Activa Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Blaze	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Blaze Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Floor	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Sensi	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Spray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Swipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Ultima	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	



PROSEPT® Ultima Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® instrusafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® instrusafe eco	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® rotasafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant I	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant R	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Burs	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Fortis	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Instru	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® impresoak	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® imprespray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
Cavex ImpreSafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Impression S	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® aspisept	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Jet D	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	

PROSEPT® Ultima Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Wipes	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® instrusafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® instrusafe eco	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® rotasafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant I	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
bepro disinfectant R	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Burs	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Fortis	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
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actisolve® imprespray	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
Cavex ImpreSafe	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Impression S	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
actisolve® aspisept	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	
PROSEPT® Jet D	10000400159-PA-NA-MYS, rev.1	27 May 2024	DNV Product Assurance AS NB 2460	DNV Product Assurance AS NB 2460	31 December 2028	

