PRISMAN healthcare innovation

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Manufacturer's declaration to extend the validity of the declaration of conformity.

SRN DE-MF-000009900

To whom it may concern,

PRISMAN GmbH has made use of the possibility of extending the validity described in more detail in the amendment to Regulation (EU) 2017/745 by Regulation (EU) 2023/607 and has received the necessary letter of confirmation (50681-Col-00, Rev.0) from DEKRA Certification GmbH (CE 0124) as Notified Body.

For the medical devices covered by the letter of confirmation in accordance with the EC certificate pursuant to Directive 93/42/EEC Annex II without Section (4) Appendix No. 50681-17-05 and No. 50681-16-04, valid until 2024-05-26, the following validity extensions apply with immediate effect:

- **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 reusable surgical instruments)

The letter of confirmation covers all products listen in the annex.

Kind regards

Dr. Simone Sartorius-Neef, QMR

Heruntergeladen von Gast (IP 216.73.217.10) am 22.11.2026 um 13:43 Uhr · sana.swiss

Annex to Notified Body Confirmation Letter 50681-CoL-00, Rev. 0

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Annex MDD:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
Instrumentendesinfektion BASIS Konz., ID 200 conc. (inkl. ZYME)/ Instrument Disinfection BASIS., ID 200 conc. (incl.Zyme)	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion FINISH, ID 710/ Instrument Disinfection FINISH, ID 710	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER PLUS Konz., IDP 400 conc./ Instrument Disinfection POW(D)ER PLUS conc., IDP 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER HIGH Konz., IDP 700 conc./ Instrument Disinfection POW(D)ER HIGH conc., IDP 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumenten Desinfektionsreiniger SOLIDSEPT Konz., IC 270 conc./ Instrument Disinfection Cleaner SOLISEPT conc. , IC 270 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM PLUS Konz.,ID 470/ Instrument Disinfection PREMIUM PLUS., ID 470 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM HIGH Konz., ID 770 conc./ Instrument Disinfection PREMIUM HIGH conc., ID770 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX BASIC Konz., ID 200 conc./ Instrument Disinfection VIREX BASIC conc., ID 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX HIGH Konz., ID 700 conc./ Instrument Disinfection VIREX HIGH conc., ID 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad PLUS, DB 400/ Dril Bath PLUS, DB 400	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad HIGH, DB 700/ Drill Bath HIGH, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad VIREX, DB 700/ Drill Bath VIREX, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX FORTE SD 710 inkl.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28

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Desinfektionstücher/ Surfacec Disinfection VIREX FORTE, SD 710 including Disinfection Wipes		
Flächendesinfektion VIREX BASIC Konz., SD 200 conc./ Surfacec Disinfection VIREX BASIC conc., SD 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX PLUS Konz., SD 400 conc./ Surfacec Disinfection VIREX PLUS conc., SD 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX HIGH Konz., SD 700 conc./ Surfacec Disinfection VIREX HIGH conc., SD 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- Wischdesinfektion BIO, RSD 410 inkl. Desinfektionstücher/ Rapis Surface Disinfection BIO, RSD 410 including Disinfection WIpes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 500 inklusive Desinfektionstücher/ Rapis Surface Disinfection MAX, RSD 500 including Disinfection WIpes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 600 inklusive Desinfektionstüchern/ Rapis Surface Disinfection MAX RSD 600 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MED, RSD 700 inklusive Desinfektionstücher/ Rapis Surface Disinfection MED, RSD 700 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Absauganlagendesinfektion Konz., SS 400 conc./ Suction System Disinfection conc., SS 400 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion Konz., SD 300 conc./ Surface Disinfection conc., SD 300 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion PROTECT Konz., SD 420/ Surface Disinfection PROTECT conc., SD 420 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion RAPID FOAM PLUS, RFD	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02

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440 inkl. Desinfektionstücher/ Surface Disinfection RAPID FOAM PLUS, RFD 400 including Disinfection Wipes		
Flächendesinfektion RAPID FOAM HIGH, RFD 740 inklusive Desinfektionstücher/ Surface Disinfection RAPID FOAM HIGH, RFD 740 including Disinfection WIpes	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
AbformdesinfektionPLUS, IM 400/ Impression Disinfection PLUS, IM 400	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Abformdesinfektion, IM 200/ Impresission Disinfection, IM 200	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfek-tion SPITOON, SP 400/ Spittoon Disinfection SPITOON, SP 400	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfek-tion NANO, SPN 700/ Spittoon Desinfection NANO, SPN 700	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
SprühWischdesinfektion, RSD 400 inklusive Desinfektionstücher/ Spitton Disinfection, RSD 400 including Disinfection Wipes	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Ätzgel/ Etching Gel	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Silanisierungsliquid SILANO/ Silanization Liquid SILANO	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion BASIC Konz., SD 200 conc./ Surface Disinfection BASIC conc., SD 200 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02

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Table 2: Devices covered by this letter and for which the NB (0124) is NOT responsible but a subject for appropriate surveillance of the corresponding devices under the certification scope of the EN ISO 13485 certificate:

Product or product group identification acc. to MDD -certificate	MDD Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate and Certificate Annex No. with revision
Prophylaxepulver/ Prohylaxe Powder PROPHY FRESH, PROPHY TOP, PROPHY SOFT, PROPHY PERIO PLUS, PROPHY SOFT PERIO	I	Prophylaxepulver/ Prohylaxe Powder PROPHY FRESH, PROPHY TOP, PROPHY SOFT,	MDR Application ID: Change Notification ÄM-50681-CN24-01 dd. 2024- 03-06 to A22051578

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Anhang XIV Konformitätserklärung
Annex XIV for EC-Declaration of Conformity

Rev.:	**06**
Stand |State:	2023-06
erstellt/geändert| Created/changed:	SO
Rezepturschlüssel| Recipe Key:	681
Basis UDI-DI:	++EPRM681EQ

Artikelnummer Kunde Item number Customer	**Artikelbezeichnung Kunde Item description customer**	**Gebinde-größe Packaging**	**Artikelnummer Lieferant Supplier item number**	**Artikelbezeichnung Supplier item description (DE)**	**Artikelbezeichnung Supplier item description (EN)**	**KS/KV-Typ KS/KV Type**	**UDI-DI**
DRS00198	Formades Plus Pure Wet Wipes XL	90 Blatt	QNA-LR090-DR01	Desinfektionstücher BIG SOFT getränkt mit Sprüh- & Wischdesinfektion RSD 400	Rapid Surface Disinfection, RSD 400 including Disinfection Wipes	KS-A	04064797009000
DRS00245	Formades PLUS PURE Wipes	80 pcs	QNA-MF080-DR01	Desinfektionstücher NR getränkt mit Sprüh- & Wischdesinfektion RSD 400	Rapid Surface Disinfection, RSD 400 including Disinfection Wipes	KS-A	04064797009017
DRS00120	Formades Schnelldesinfektion PLUS Pure	5 L	681-05000-DR02	Sprüh- und Wischdesinfektion RSD 400 inkl. Desinfektionstücher	Rapid Surface Disinfection, RSD 400 including Disinfection Wipes	-	04064797008997
DRS00119	Formades Schnelldesinfektion PLUS Pure (Fl129)	1 L	681-01000-DR02	Sprüh- und Wischdesinfektion RSD 400 inkl. Desinfektionstücher	Rapid Surface Disinfection, RSD 400 including Disinfection Wipes	-	04064797008980

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