

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

SNR 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 listed in the annex.

Kind regards

Dr. Simone Sartorius-Neef, QMR

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)	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	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.	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.	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.	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	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.	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.	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., ID700 coc.	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	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	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	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. Desinfektionstücher	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 BASIC Konz., 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.	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.	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	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	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	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	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.	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.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
FlächendesinfektionPROTECT Konz., SD 420	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 440 inkl. Desinfektionstücher	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 HIGH, RFD 740 inklusive Desinfektionstücher	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	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	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfektion SPITOOON, 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
Mundspülbeckendesinfektion 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	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Ätzel	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Silanierungsliquid 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.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02