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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 listed in the annex.

Kind regards

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Dr. Simone Sartorius-Neef, QMR

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## 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 |

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

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

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/<br>Prohylaxe Powder<br>PROPHY FRESH, PROPHY<br>TOP, PROPHY SOFT,<br>PROPHY PERIO PLUS,<br>PROPHY SOFT PERIO | I                         | Prophylaxepulver/<br>Prohylaxe Powder<br>PROPHY FRESH, PROPHY<br>TOP, PROPHY SOFT,       | MDR Application ID: Change Notification ÄM-<br>50681-CN24-01 dd. 2024- 03-06 to<br>A22051578 |

# **Anhang XIV Konformitätserklärung**

## **Annex XIV for EC-Declaration of Conformity**

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

| Artikelnummer<br>Kunde<br>Item number<br>Customer | Artikelbezeichnung<br>Kunde<br>Item description<br>customer | Gebinde-<br>größe<br>Packaging | Artikelnummer Lieferant<br>Supplier item number | Artikelbezeichnung<br>Supplier item description<br>(DE)                      | Artikelbezeichnung<br>Supplier item description<br>(EN)          | KS/KV-Typ<br>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 (FI129)              | 1 L                            | 681-01000-DR02                                  | Sprüh- und Wischdesinfektion RSD 400 inkl. Desinfektionstücher               | Rapid Surface Disinfection, RSD 400 including Disinfection Wipes | -                       | 04064797008980 |