CE Declaration of Conformity

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices

Medical Device	**Family: Protective Clothing**
Catalogue number (REF)	**Surgical mask:** - Suavel® Protec Plus (Typ II) REF: 80-955MP, 80-956 - Suavel® Protec (Typ II) REF: 80-900, 80-901 - Suavel® Protec (Typ II R) REF: 80-902 - Suavel® Protec Plus IIR (Typ II R) REF: 80-957 - Suavel® Comfort Plus (Typ II) REF: 80-410M - Suavel® Comfort (Typ II) REF: 80-400, 80-402 - Suavel® Antifog (Typ II) REF: 80-470M - Suavel® Antifluid (Typ II R) REF: 80-455M - Suavel® Sensima (Typ II) REF: 80-440M **Gowns non-steril:** - BeeSana® PP-Schutzmantel 35 g REF: 3686 / 3700 - BeeSana® PP-Kittel 23 g REF: 3684 / 3685 / 3699 / 3729 / 4685 / 4699 - BeeSana® PP/PE-Kittel 26 g REF: 4698, 4698XL - BeeSana® SMS-Kittel 40 g REF: 3597 - BeeSana® SMS-Kittel 15 g REF: 3598 - PE-Einmalschürze REF: 3591/ 3690/ 3691/ 3692/ 3687/ 3688/ 3694/ 3696/ 3697 **Head caps:** - Suavel® Apollo (REF 70-131G) - Suavel® Astrid (REF 70-121B, 70-121G, 70-121W) - Suavel® Astrid XL (REF 70-124G, 70-124W) The list of products which are alternatively marketed with other brand names (private label) and which are covered by this Declaration of Conformity are listed in Annexes 1 - 10.
Basis UDI-DI according to Anhang VI, Part C	GMN4200164S002protclothns62
Intended use	The devices are used for protection from contamination of patients and users. The protective gowns are not intended for the use in surgical or other invasive procedures.
Medical device class according to Annex VIII	I

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Manufacturer	Meditrade GmbH Medipark 1 D-83088 Kiefersfelden
Single Registration Number according to Article 31	The SRN has been requested

We hereby declare in our own responsibility the conformity of the above medical device with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices.

Meditrade hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, with other relevant Union provisions which require the issuance of an EU declaration of conformity.

Common specifications applied:

There are no common specifications for these devices according to Article 9 of Regulation (EU) 2017/745.

Chosen conformity assessment procedure	Annex IV
CE-mark since	1998
Validity of this CE Declaration of Conformity	28.05.2022

Kiefersfelden, 28.05.2021

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Person responsible for regulatory compliance

Martin Unterberg