



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 - Gowns
<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p>Gowns, non-sterile</p> <ul style="list-style-type: none"> - BeeSana® PP-Schutzmantel 35 g (REF: 3700) - BeeSana® PP-Kittel 23 g (REF: 3684, 3685, 3699, 3729, 4685, 4699) - BeeSana® PP/PE-Kittel 26 g (REF: 4697, 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) </div>	
Intended use	The medical device is used to protect the patient from contamination. The product is used in healthcare settings outside the emergency medical, surgical and invasive application areas. Wearing the medical device in the sick and nursing area reduces the spread and/or spread of germs and/or contamination. The product is not personal protective equipment according to Regulation (EU) 2016/425. Only for applications with dry conditions & not intended for applications with high mechanical forces (e.g. physically carrying patients or heavy, sharp objects). Open back gown for applications with little anticipated risks originating from the user's back area. Not an isolation gown - do not use for risk group 3 patients (e.g. patients with immune deficiencies).
Basis UDI-DI according to Annex VI, Part C	GMN42500164S002protclothns62
Medical device class according to Annex VIII	I
Chosen conformity assessment procedure	The technical documentation according to Annex II and Annex III of Regulation (EU) 2017/745 is available.
CE-mark since	Since 1998 according to 93/42/EEC and since 05.2021 according to Regulation (EU) 2017/745
Validity of this CE Declaration of Conformity	25.12.2026



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Manufacturer	Meditrade GmbH Medipark 1 83088 Kiefersfelden
Single Registration Number according to Article 31	DE-MF-000008937

We hereby declare in our sole 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.

Kiefersfelden, 25.01.2024

Martin Unterberg, PRRC

Person responsible for regulatory compliance under Article 15 of Regulation (EU) 2017/745, Meditrade GmbH