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 – Surgical Masks**

Surgical Masks, non-sterile

- 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 IIR (REF: 80-957)
- Suavel® Comfort Plus, Typ II (REF: 80-410M)
- Suavel® Comfort, Typ II (REF: 80-400)
- Suavel® Comfort, Typ IIR (REF 80-402)
- Suavel® Antifog, Typ II (REF: 80-470M)
- Suavel® Antifluid, Typ IIR (REF: 80-455M)
- Suavel® Sensima, Typ II (REF: 80-440M)

Intended use	The devices are used for the protection of patients from contamination. Wearing of the medical devices by the user, patient or other persons, reduces the spread and/or cross contamination of germs and/or other infectious materials.
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	05.03.2026

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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, 05.03.2023

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Martin Unterberg, PRRC

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