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: Examination gloves, non-sterile**

Examination gloves made of Latex, powdered

- Reference (REF 1121)

Examination gloves made of Latex, powderfree

- Gentle Skin® sensitive (REF 1221RT)
- Gentle Skin® classic (REF 1221R)
- Gentle Skin® classic x-long (REF 1223)
- Gentle Skin® grip (REF 1221GRIP)
- Gentle Skin® compact + (REF 1221I)
- Gentle Tec (REF 1229)
- Gentle Skin® HiRisk (REF 1228)
- Gentle Skin® Aloecare (REF 1231)
- Gentle Skin® black) (1224)

Examination gloves made of Nitrile, powderfree

- Nitril® 3000 (REF 1280)
- Nitril® 3000 x-long blue / Nitril® x-long (1282)
- Nitril® NextGen® (REF 1283)
- Nitril® BestGen® (REF 1286)
- Nitril® Magenta (REF 1287)
- Nitril® Black (REF 1284)
- Nitril® Viola (REF 1285)
- Nitril® Sensory® white (REF 2280)
- Nitril® Sensory® blue (RE 2283)
- Nitril® Sensory® violet blue (REF 2285)
- Nitril® GreenGen® (REF 1293)
- Nitril® LIOX® (REF 2284)

Examination gloves made of Vinyl, powderfree

- Vinyl 2000 PF (REF 1251)
- Vinyl 2000 Stretch PF (REF 1253)
- Vinyl BlueGen (REF 1255)

Intended use	The non-sterile examinations gloves are intended for the protection from contamination of patients and user.
Basis UDI-DI according to Annex VI, Part C	GMN42500164H002exglovesnsF2

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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	27.05.2027

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, 28.05.2024

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Martin Unterberg, PRRC

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