EC DECLARATION OF CONFORMITY

- Declaration as Medical Device, Class I -

MANUFACTURER : BIMEL ITHALAT IHRACAT VE TICARET ANONIM SIRKETI
GIYIM SANATKARLARI 1A BLOK, SK.N:204 BASAKSEHIR /IKITELLI
OSB, 34490 ISTANBUL, TURKEY IKITELLI VERGI DAIRESI / 1751011755

SRN (Single Registration Number): TR-MF-000045590

Product Type, GMDN CODE :

Nitrile examination glove, non-sterile, powder-free, class I - 56286

Basic UDI-DI: 868112400ELV2

Brand : CoreMed

Model : Nitrile

Certified by:

Standard: ISO 13485:2016
Issuer: GCR CERT
Cert. No.:GCR/CERT - 09.2026.008500
Valid until: 27.09.2027

are in conformity with the general safety and performance requirements of the Regulation (EU) 2017/745 as well as the conformity assessment procedure according to Annex II, Annex III und Annex IV (self declared).

In harmony with the classification rule of Regulation (EU) 2017/745 Annex VIII, following rule 5, the products are certified as medical device class I.

Furthermore, they comply with the following harmonized standards.

| EN 455-1:2020+A1:2022 | EN 455-2:2015 | EN 455-3:2015 | EN 455-4:2009 |

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