

EC Declaration of Conformity (DoC)

1. Medical face mask Sono MN Type E5
by
2. Dr. Freist Automotive GmbH, Alte Heerstr. 21, 38644 Goslar, Germany.
3. We declare under our sole responsibility for the product:
4. Part of this declaration is a medical face mask type II „Sono MN E5“ (see also material data sheet 07/2020) with a nose clip of nickelfree aluminium and elastic bands. This unsterile face mask should be used in contact with patients to reduce the probability of infections for both parties.
5. The product described in 4 is in conformity with the relevant Union harmonisation legislation 93/42/EWG.
6. The medical face mask fulfills the technical specification DIN EN 14 683:2019 + AC:2019 vom Oktober 2019 (s. Prüfbericht B 24463 und Zertifikat 2024463/154 vom 20.11.2020, Fa. HygCen, Österreich) and in addition the german „Medizinproduktegesetz“. A design- and process FMEA for the product shows controlable risks.
7. The manufacturer has a certified quality management system according to ISO 9001:2015 (Dekra 7.10.2020).).

Signed by or for DFA GmbH.

Place and date of issue: Goslar, 20.11.2020



Dr. R. Dopheide (CEO)



A. Hannig (CEO)