

EC Declaration of Conformity (DoC)

1. Medical face mask Sono MN Type E6
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 IIR „Sono MN Type E6“ (see also material data sheet E6) 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 EN 14 683:2019 (October 2019) (Certificate Number 2025679/116, 2020-10-07, Fa. HygCen, Austria) and in addition the german „Medizinproduktegesetz“. A design- and process FMEA for the product shows controllable 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, 19.10.2020

Dr. R. Dopheide (CEO)



A. Hannig (CEO)

