EU – Declaration of Conformity

1. Name/address of the manufacturer: MAPA GmbH
Industriestraße 21 – 25
27404 Zeven, Germany

SRN: DE-MF-000017639

2. We declare under our sole responsibility that for the designated product, which has been manufactured in accordance with the Technical Documentation

TD 050 Revision 2

and which is documented in the batch documentations, complies with the provisions of the following regulation:

(EU) 2017/745 — Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

3. Basic-UDI-DI: 400860 NASAU 0000 05FE

4. Product and trade name: NUK NASAL DECONGESTER

Article numbers:
10.256.065
10.750.997
10.751.000
10.020.322 (bulk)

5. Medical device class: I

6. The conformity of the listed products with the essential protection requirements of the Regulation is demonstrably and fully in compliance with the following harmonized standards:

7.

DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
DIN EN ISO 14971 :2020-07	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
DIN EN ISO 10993-1 :2021-05	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
DIN EN 71-3 :2021-06	Safety of toys - Part 3: Migration of certain elements

8.	Notified body	Not applicable for medical device of class I
9.	Additional information:	Document validity until [yyyy-mm-dd] 2025-06-09
10.	Place of issue, Date [yyyy-mm-dd]	Zeven, 2021-06-09

Digital unterschrieben von Günter STEITZ
Datum: 2022.02.10 16:30:48 +01'00'

i.A. Guenter STEITZ (Quality Management)
Signed for and on behalf of Alexander Du Chesne (Director Quality Management)