



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 049 Revision 2

and which is documented in the batch documentations, complies with the provisions of the following directives / regulations:

(EU) 2017/745 REGULATION (EU) 2017/745 of the European

Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives

90/385/EEC and 93/42/EEC

(EU) No 10/2011 Commission Regulation (EU) No 10/2011 of 14

January 2011 on plastic materials and articles intended to come into contact with food

(EC) No 1907/2006 Regulation (EC) No 1907/2006 of the European

Parliament and of the Council of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals

Agency

3. Basic-UDI-DI: 400860 MIPUEL 0000 01HW

4. Product and trade name: NUK Electric Breast Pump

Article numbers: for First Choice +

10.252.129 10.749.106 10.749.107 10.749.114



MAPA GmbH

27404 Zeven, Industriestraße 21-25 · Germany · Tel. +49 4281 73-0 · Fax +49 4281 73-241 · <u>www.mapa.de</u> County Court Tostedt HRB 120049 · General Manager: Dr. Ralf Holschumacher, Sean Beckstrom



:2016

:2021



for Nature Sense

10.252.130 10.252.132 10.749.104 10.749.105 10.749.108 10.749.111 10.749.112



5. Medical device class: I

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

7. EN 62366-1 Medical devices - Part 1: Application of usability

:2017 engineering to medical devices

EN 60601-1 Medical electrical equipment - Part 1: General :2006/A1:2013

requirements for basic safety and essential

performance

EN 60601-1-2 Medical electrical equipment - Part 1-2: General

requirements for basic safety and essential

performance - Collateral standard: Electromagnetic

disturbances - Requirements and tests

EN 60601-1-11 Medical electrical equipment - Part 1-11: General

:2016 requirements for basic safety and essential

> performance - Collateral standard: Requirements for medical electrical equipment and medical electrical

systems used in the home healthcare environment

DIN EN ISO 10993-1 Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management

process

EN 14350 Child use and care articles - Drinking equipment

DIN EN ISO 15223-1 Medical devices - Symbols to be used with medical

:2017 device labels, labelling and information to be

supplied - Part 1: General requirements

8. Notified body Not applicable for medical devices class I

9. Additional information: Document validity until [yyyy-mm-dd]: 2025-02-15

MAPA GmbH

27404 Zeven, Industriestraße 21-25 · Germany · Tel. +49 4281 73-0 · Fax +49 4281 73-241 · www.mapa.de County Court Tostedt HRB 120049 · General Manager: Dr. Ralf Holschumacher, Sean Beckstrom







10. Place of issue, Date [yyyy-mm-dd]: Zeven, 2021-02-15

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