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

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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 10/2011of 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 LUNA

Article numbers: 10.749.082
10.252.096

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 :2017	Medical devices -Part 1: Application of usability engineering to medical devices
	EN 60601-1 :2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2 :2016	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
	DIN EN ISO 10993-1 :2021	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 :2017	Medical devices - Symbols to be used with medical 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]: 2025-05-31
10.	Place of issue, Date [yyyy-mm-dd]:	Zeven, 2022-01-12

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

MAPA GmbH
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