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
2001/95/EC	Directive 2001/95/E of the European Parliament and of the Council of 3 December 2001 on general product safety
10/2011/EU	Commission Regulation 10/2011/EU of 14 January 2011 on plastic materials and articles intended to come into contact with food
93/11/EC	Commission Directive 93/11/EC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
94/62/EC	Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste

3. Basic-UDI-DI: 400860 SATRA 0000 04LD

4. Product and trade name: NUK THERAPEUTIC TRAINER size S and L

Article numbers: 10.107.020
10.107.021

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 1400 :2013 + Al:2014	Child use and care articles - Soothers for babies and young children - Safety requirements and test methods
	DIN EN 14971 :2013-04	Medical devices- Application of risk management to medical devices
	DIN EN 12868 : 1999-12	Child use and care articles - Methods for determining the release of Nnitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
	DIN EN ISO 10993-1 :2021	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management system
	DIN EN 1041 :2013-12	Information supplied by the manufacturer of medical devices
	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] 2026-03-31
10.	Place of issue, Date [yyyy-mm-dd]	Zeven, 2022-04-01

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