EU - Declaration of Conformity

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

Product description: CONDOMS MADE OF NATURAL RUBBER LATEX

with reservoir and packed into sealed foil:

- cylindrical, smooth, coloured or transparent with pure silicone oil, or additionally flavoured
- cylindrical, smooth or contoured, coloured or transparent with pure silicone oil, or additionally flavoured

Trade mark: Billy Boy, Blausiegel, Fromms, R3

Medical device of class: Class IIb according directive EC 93/42/EEC, annex IX, rule 14

We declare under our sole responsibility, that all condoms listed with their Batch-Numbers are manufactured according to the following Technical Documentation

TD 031 Revision 4.1 since 22nd Oct. 2020

and documented in the general batch recording and comply with the provisions of the Council Directive **93/42/EEC** of 14 June 1993 concerning medical devices.

The listed products are completely and demonstrably in conformity with the following standards or other normative documents:

EN ISO 4074	Natural latex rubber condoms - Requirements and test methods
DIN EN ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management system
DIN EN ISO 10993-5	Part 5: Tests for in vitro cytotoxicity
DIN EN ISO 10993-10	Part 10: Tests for irritation and skin sensitization
DIN EN ISO 10993-12	Part 12: Sample preparation and reference materials
DIN EN ISO 14971	Medical devices- Application of risk management to medical devices
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

Conformity assessment procedure:	according to Annex II of the Directive 93/42/EEC, excluding section 4.
Registration number:	HD 60090842 0001
Notified body:	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg **CE 0197**

Place of issue, Date: Zeven, 19th May 2021

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

MAPA GmbH
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Amtsgericht Tostedt HRB 120049 · Geschäftsführer: Dr. Ralf Holschumacher, Sean Beckstrom

CORRIGENDUM/ADDENDUM

to EU-Declaration of Conformity for Billy Boy, Blausiegel, Fromms, R3 Latex Condoms, **signed 19th May 2021**

Document name	MEDKO-EU-DOC
Release No.	01
Date	26.04.2024
Number of Pages	1

Reason for the correction/addition:

With the declaration of invalidity of the MDD on 26 May 2021, this Declaration of Conformity (signed 19th May 2021) may no longer be reissued or revised. All subsequent significant changes in the normative and legal requirements of these products are given in this document.

a) With the invalidity of the MDD, the harmonised standard DIN EN 1041 was also withdrawn and replaced by the successor standard DIN EN ISO 20417, which is related to the MDR.

b) The DoC refers to TD-031-4-1. However, the current valid technical documentation is "TD-031-08"

c) The SRN is "DE-MF-000017639"

d) The Basic UDI-DI is "4008600 KONDOM000007 E8"

e) Acc. EU 2017/745 Art. 120 (2) MDD - Certificates issued by the notified body after May 25, 2017, and still valid on May 26, 2021, remain valid until Dec. 31, 2028

Acc. to our notified body, CE 197, this also implies that DOCs issued for the respective products shall not be renewed but remain valid accordingly

G. Steitz
Digital unterschrieben von Günter Steitz
Datum: 2024.04.29 08:53:24 +02'00'

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

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