PLEASURE LATEX PRODUCTS SDN. BHD.

Company No.: 199601029785 (402137-W)

EU DECLARATION OF CONFORMITY

We, **PLEASURE LATEX PRODUCTS SDN. BHD. (PLP)** declare that the Non-medicated Natural Rubber Latex Ultrasonic Transducer Probe Covers (with basic UDI-DI: 955501242PC0015A) that manufactured by us (PLP SRN: MY-MF-000016199) is classified as a Class IIa medical device (Annex VIII Rule 5). The Probe Covers are in conformity with the **Regulation (EU) 2017 / 745.**

The intended use of our Probe Covers:
As a protective cover in avoiding contamination of ultrasonic transducer probes by bodily fluids. To facilitate cleaning and sanitization of the probes.

Probe Covers manufactured by PLP are declared in conformity with harmonized standard:

- EN ISO 4074:2015 Natural Rubber Latex Male Condoms – Requirements and Test Methods.
  a) Bursting test at Inspection Level S-4 with AQL 2.5 (instead of Inspection Level G-1 with AQL 1.5).
  b) Freedom from hole test at Inspection Level S-4 with AQL 1.0 (instead of Inspection Level G-1 with AQL 0.25).
  c) Visible Defects test at Inspection Level S-4 with AQL 1.0 (instead of Inspection Level G-1 with AQL 0.4).
  d) Individual container with visibly open seals test at Inspection Level S-4 with AQL 0.65 (instead of Inspection Level G-1 with AQL 0.4).

The standards used to demonstrate compliance are;

- EN ISO 20417:2021, Information to be supplied by manufacturer,
- ISO 2859-1:1999, Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection,
- EN ISO 13485:2016, Medical devices – Quality Management Systems – Requirements for regulatory purposes,
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,
- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity ,
- ISO 10993-10:2021, Biological evaluation of medical devices – Part 10: Tests for skin sensitization,
- ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation,
- ISO 11737-1:2018 / Amd 1:2021, Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1,
- EN ISO 14971:2019, Medical devices – Application of risk management to medical devices,
- EN ISO 15223-1:2021, Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements,
- EN 62366-1:2015 +A1:2020 / IEC 62366-1:2015 + A1:2020, Medical devices: Application of usability engineering to medical devices,
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems,

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- ASTM D4332-14, Standard Practice for Conditioning Containers, Packages or Packaging Components for Testing,
- ASTM D5712(2020), Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method,
- EN 14372:2004, Determination of phthalates by GC-MS
- Norme Francaise, NF S97-034 (Dec 2007), Additional lubricants and other medicinal and nonmedical preparations intended for or likely to come into contact with natural rubber latex condoms – Compatibility Specifications and test methods,
- Medical Device Regulation (EU) 2017/745,
- IMDRF / RPS WG/N9 (edition 3) FINAL: 2019 Non In-Vitro Diagnostic Device Market Authorization Table of Contents,
- Summary Technical Documentation for Demonstration Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED), GHTF/SG1/N011:2008,
- Regulation EC 1907 / 2006 amended by EC 552/2009 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Compliance,
- Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In-vitro Diagnostic Medical Devices Version 3 (September 2023),
- MDCG 2021-24, Guidance on classification of medical devices (October 2021),
- MDCG 2021-13 rev.1, Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorized representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR (July 2021),
- MDCG 2021-1, rev.1, Guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional (May 2021),
- MDCG 2020-15, MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States (August 2020),
- MDCG 2019-5, Registration of legacy devices in EUDAMED (April 2019),
- MDCG 2019-4, Timelines for registration of device data elements in EUDAMED (April 2019),
- MDCG 2021-12, FAQ on the European Medical Device Nomenclature (EMDN) (May 2021),
- MDCG 2023-3, Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices (February 2023),
- MDCG 2022-21, Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 (December 2022),
- MDCG 2021-5, Guidance on standardization for medical devices (April 2021),
- MDCG 2022-7, Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (May 2022),
- MDCG 2021-19, Guidance note integration of the UDI within an organization's quality management system (July 2021),
- MDCG 2018-1 Rev.4, Guidance on Basic UDI-DI and changes to UDI-DI (April 2021),
- MDCG 2019-1, MDCG guiding principles for issuing entities rules on Basic UDI-DI (January 2019),

- MDCG 2018-7, Provisional considerations regarding language issues associated with the UDI database (Annex VI, Part A Section 2 and Part B of the Medical Device Regulation (EU) 2017/745 (MDR) and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR)) (October 2018),
- MDCG 2018-6, Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (October 2018),
- MDCG 2019-7 Rev.1, Guidance on Article 15 of the Medical Device Regulation (MDR) and in-vitro Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance'(PRRC) (December 2023),
- MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC, A guidance for manufacturers and notified bodies, April 2020,
- MDCG 2024-1, Guidance on the vigilance system for CE marked devices, Jan 2024.

The Quality Management System implemented by PLP is subjected to the procedure set out in Chapter I and III of Annex IX of Regulation (EU) 2017 / 745 under the supervision of Notified Body Number 0482, DNV MedCert Certification Body.

Quality Management System
- Certificate : EN ISO 13485:2016
- Certificate no.: 7536GB445230608
- Expiry date : 29-April-2026

EMDN code of Latex Probe Cover : T030199
GMDN code of the Latex Probe Cover: 44713

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We declare that this EU Declaration of Conformity is issued under the sole responsibility of Pleasure Latex Products Sdn. Bhd.

PLEASURE LATEX PROD. SDN. BHD. (402137-W)

Irene Ting
Quality Assurance Manager,
For and on behalf of Pleasure Latex Products Sdn. Bhd.
Place of Issue: Jeram, Malaysia
Date: 15th May 2024