EU Declaration of Conformity

MANUFACTURER:	APOLLO HEALTHCARE TECHNOLOGIES LTD		
MFG. ADDRESS	Holme Street, Liversedge West Yorkshire, WF15 6JF, United Kingdom		
PRODUCT NAME:	Apollo 5 Premium	**PRODUCT CODE:**	APH183

CLASSIFICATION:	**Class**	**MDD Classification Rule**	**Conformity Assessment**	**NBOG Code[1]**	**GMDN Code[2]**
	IIa	Annex IX, Rule 9	Annex V	MD1103	47478

[1] Reference NBOG BPG 2009-3;
[2] Reference Global Medical Device Nomenclature™ (GMDN).

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE PRODUCT IS IN CONFORMITY WITH THE BELOW APPLIED STANDARDS.

STANDARDS APPLIED	**DESCRIPTION**
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 60601-1:2015+A1-2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN IEC 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN IEC 60601-1-11:2015 (Edition 2.0)	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304:2009/A1:2015	Medical device software - Software life cycle processes
EN IEC 62366-1:2015 + AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 7010:2011 (Second Edition)	Graphical symbols - Safety colours and safety signs - Registered safety signs
BS 7068:1989	Specification for alternating pressure air mattresses
EN ISO 15223-1: 2016 (Third edition)	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2010	Biological evaluation of medical devices - Part 6: Tests for in vitro cytotoxicity
EN ISO 10993-10:2010 (Third Edition)	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

NOTIFIED BODY:	TÜV Rheinland LGA Product GmbH Tillystraße 2, 90431 Nürnberg, DEUTSCHLAND	IDENTIFICATION NUMBER:	0197

EC	REP	PaMed Consulting Karol Pawelec, ul. Jeleniowska 202A/54, 25-564 Kielce, Poland Tel/Fax: +48 507 833 787 Email: ar@pamed-consulting.eu

EC CERTIFICATE #:	DD 2285935-1		
START OF CE-MARKING:			
PLACE OF ISSUE	Holme Street, Liversedge, West Yorkshire, WF15 6JF, United Kingdom	DATE OF ISSUE	14 October 2022

Product code	Product Description	Serial Number Pump	Serial Number Mattress
APH183	Apollo 5 Premium	APH2712103574	APH1832103091

SIGNATURES		
PRINT NAME	POSITION	SIGNATURE
MADHU SABHARWAL	MANAGEMENT REPRESENTATIVE	Madhu Sabharwal Madhu Sabharwal (Oct 19, 2022 19:42 GMT+1)
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