	<b>Title:</b> Declaration of Conformity		
	<b>Effective Date:</b> 04 Dec 24	<b>Document #:</b> RA-TMP-2.0.6	<b>Revision #:</b> 2.0



**Declaration of Conformity 93/42/EEC as amended**  
**006 MDD 2018-17-12**

<b>1. Product identification</b>	
1.1 Product/Device name	Hybrid Mattress Family
1.2 List of products	See Appendix 1
1.3 Intended purpose	The intended purpose of Hybrid Mattress System is to help and reduce the incidence of pressure ulcers while optimizing patient comfort.
1.4 Basic UDI-DI	TBC
1.5 GMDN Code & Term	63241 Alternating-pressure bed mattress system
1.6 EMDN Code & Term	V080701 Active anti-bedsore medical mattresses
1.7 Medical Device TF name	Technical Files for Hybrid Family
<b>2. Manufacturer</b>	
2.1 Name	Apollo Healthcare Technologies Ltd.
2.2 Address	Unit A1 Gildersome Spur, Morley, Leeds, West Yorkshire, LS27 7JZ, United Kingdom
2.3 SRN	TBC
<b>3. Authorised Representative in Europe (EU Rep)</b>	
3.1 Name	PaMed Consulting Karol Pawelec
3.2 Address	Jeleniowska Street 202A/54, 25-564 Kielce, Poland.
3.3 SRN	PL-AR-000041181
<b>4. Notified Body</b>	
4.1 Name	TÜV Rheinland LGA Product GmbH
4.2 Identification number	0197

**5. Means of Conformity**

We herewith declare that the above-mentioned products meet the provisions of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by directive 2007/47/EC' And comply with Essential Requirements of the Directive. All supporting documentation is retained under the premises of the manufacturer.

5.1 Conformity Assessment Route

Annex V

5.2 Risk Classification

Ila

5.3 Standards Applied

EN 60601-1: 2006 + A1:2013  
EN 60601-1-2:2015  
ISO 10993-1:2009  
EN ISO 13485:2016  
EN ISO 14971:2019  
EN ISO 15223-1:2016

5.4 Expiry Date

26 May 2024

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.


5.5 Name & Position

David Fletcher General Manager

5.6 Place of issue

Unit A1 Gildersome Spur, Morley, Leeds, West Yorkshire, LS27 7JZ, United Kingdom

5.7 Signature

  
D Fletcher (Feb 10, 2025 15:43 GMT)

5.8 Date

10/02/2025

Annex 1. List of products

List of products covered by this Declaration of Conformity		
Product code	Product Name	UDI-DI
APH166	Morpheus Air Hybrid Mattress System	TBC
APH272 (Hybrid)	Cronus Digital Pump (Hybrid)	TBC
APH166M	Morpheus Air Mattress Only	TBC
APH166Z	Morpheus Air Zero System	TBC
APH500	HERA Pump	TBC

END OF DOCUMENT

# RA-TMP-2.0.6\_Declaration\_of\_Conformity\_Rev2 Hybrid Family MDD + hera

Final Audit Report

2025-02-10

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