HOSPITECH
RESPIRATION

Hospitech Respiration Ltd.
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Hospitech EC Declaration of Conformity

Manufacturer: Hospitech Respiration Ltd. 15 Atir Yeda St, Kfar Saba,4464312, Israel
SRN No: IL-MF-000018143

Place and Date of Declaration of Conformity: in Hospitech Ltd. August 15, 2023. Hospitech Respiration Ltd. is exclusively responsible for the declaration of conformity

Declaration objective: to describe and declare conformance with the relevant EU legislation and harmonized standards for the AGCuffill.

We hereby declare, in accordance to the confirmation letter received on 13 August 2023 from MDC, (Hospitech's appropriate EU Notified Body), that the following products meet the current transitional provisions according to Article 120 of the Medical Device Regulation MDR (2017/745), and as amended by Regulation (EU) 2023/607, and as a consequence, the existing EC Certificate of Conformity for AG Cuffill is valid until 2028-12-31.

Products: AG Cuffill Model HSCUFF0031: Measurement range 0-99 mmHg
AG Cuffill Model HSCUFF0041: Measurement Range 0-99 cmH2O

Classification according to MDD Annex IX (Rule 1): I(m)

Conformity Assessment Route: MDD Annex II Excluding Sect.4

EC CERTIFICATE NO	NOTIFIED BODY	NOTIFIED BODY NO
D1208200010	MDC Medical Device Certification GmbH Kriegerstraße 6,70191 Stuttgart/ Germany	0483

Standards applied: See next page

European Authorized Representative (EU Rep) MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany, SRN number: DE-AR-000000002

We state that this declaration of conformity is valid for all AG Cuffill devices as long as no changes in the product are done and/or the certificate issued by the notified body has not expired. In case of any changes in the product, changes in Hospitech address, logo or when the declaration passed the valid date below, a new revised declaration will be issued.

Name: Yoav Venkert **Date: August 15, 2023** **Valid until: December 31, 2028**

Title: Hospitech CEO **Signature:** CE 0483

Regulations and Standards Applied:

(EU) 93/42/EEC	Medical Device Directive
(EU) 2017/745	Medical Device Regulation
(EU) 2023/607	amending Regulations (EU) 2017/745
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14971-1:2012 (ISO 14971:2007)	Risk management for medical devices
EN 60601-1:2006/A1:2013 (IEC 60601-1:2006/Al:2012)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Ed. 3.1)
EN 60601-1-2:2015 (lEC 60601-1-2:2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard; Electromagnetic Compatibility-Requirements and Tests
EN 60601-1-6-2010 (lEC 60601-1-6:2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard; Usability
EN 62366:2008 (IEC 62366:2007AMD1:2014)	Medical devices-Application of usability engineering to medical devices
EN ISO 15223-1:2016	Graphical Symbols for Use in the Labeling of Medical Devices
EN 1041:2008/A1:2013	Information supplied by the manufacturer with medical device
EN 62304:2006:AC 2008 (lEC 62304:2006)	Medical device software - Software life-cycle processes
EN ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices