EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Hospitech Respiration Ltd.
15 Atir Yeda Street
Kfar Saba, 446312
Israel

for the scope

AG cuffill device for
cuff pressure measurement and regulation

has introduced and applies a

Quality System

for the aspects of manufacture concerned with the conformity
of the products with metrological requirements.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2018-08-16
Valid until	2023-08-15
Registration no.	D1208200010
Report no.	P18-00667-126960
Stuttgart	2018-08-15

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

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HOSPITECH
RESPIRATION

13 August 2023

Self-Declaration on the Validity of AG Cuffill MDD Certificate

Confirmation on the applicability of Regulation (EU) 2023/607 on the amended transitional provisions for certain medical devices and in vitro diagnostic medical devices

Name and address of manufacturer: Hospitech Respiration Ltd. 15 Atir Yeda St. Kfar-Saba 4464312

This self-declaration is issued on the sole responsibility of the manufacturer Hospitech Respirations Ltd. and confirms the applicability of Regulation (EU) 2023/607 for:

Product name: AG Cuffill
Models/ REF: HSCUFF0041 and HSCUFF0031
Risk class (according to Annex VIII MDR): I(m)
Certificate No.: D1208200010
Effective date of certificate: 15-August-2018
Original Expiry date of certificate: 15-August 2023
End date of the transition period: 31 December 2028 (The expiration date of the MDD certificate for AG Cuffill is after 20th March 2023 allowing this date under regulations 2023/607), under Article 1, clause 3(b))

This self-declaration confirms that

- The AG Cuffill, a conformity assessment procedure according to Annex II (excluding Sect.4) of Directive 93/42/EEC was carried out with the participation of the Notified Body MDC (identification number 0483) and the fulfilment of the requirement was confirmed by issuing a Certificate on 2018-08-16 with the Certificate Number D1208200010; the certificate was valid on 26th May 2021 and on 20th March 2023 and was not withdrawn;
- the above-mentioned product continues to comply with Directive 93/42/EEC
- there are no significant changes in the design and intended purpose;
- the above-mentioned product does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- Hospitech Respiration Ltd. is going to put no later than 26 may 2024 a quality management system in accordance with Article 10(9) of MDR, in place.
- Hospitech Respiration Ltd complies with the MDR Article 120 requirements related to PMS, vigilance, market surveillance and registration of actors and devices since 26 May 2021
- In accordance with the current transitional provisions according to Article 120 (3a. (b)) of MDR, and as amended by Regulation (EU) 2023/607, the existing EC Certificate of Conformity with current validity until 2023-08-15 shall remain valid beyond that date and until 2028-12-31. Please see attached confirmation letter, on this matter from 13 August 2023, from MDC (Hospitech's NB).
- At the request of MDC (Hospitech's NB), Hospitech Respiration Ltd has lodged a new formal application on 2023-03-28 for MDR certification in accordance with Section 4.3, first paragraph, of Annex VII to Regulation (EU) 2017/745 for conformity assessment in respect for the above-mentioned products or in respect of a product intended to substitute the product. Please see attached confirmation letter, on this matter.

Signature, Place and Date

Yoel Bergman, QA/RA Director,

Hospitech Respiration Ltd, 13 August 2023

Hospitech Respiration Ltd.
15 Atir Yeda Street
Kfar Saba, 4464312
Israel

Notified Body Confirmation Letter

Reference: D1208200017

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Hospitech Respiration Ltd.
15 Atir Yeda Street
Kfar Saba, 4464312
Israel
SRN: IL-MF-000018143

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Stuttgart, 2023-08-10

Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AG100s control unit B-7290015409109Y	Class IIa	N/A	D1208200011 NB 0483
AG Connection kit B-729001540911A2MU	Class IIa	N/A	D1208200011 NB 0483
AG ETT B-7290015409009VNZ	Class IIa	N/A	D1208200014 NB 0483
AG CUFFILL B-07290015409001	Class Im	N/A	D1208200010 NB 0483

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	*N/A*	*N/A*	*N/A*

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-08-10	D1208200017	Initial