Manatec
21 rue du stade, Petit Ebersviller
57730 FOLSCHVILLER, FRANCE
phone : +33 3 72 82 50 00 ▪ fax : +33 1 30 74 46 48

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MANATEC
Manufacturer address (headquarters)	21 rue du stade, Petit Ebersviller 57730 FOLSCHVILLER, FRANCE
Manufacturing site	10 bis, rue Jacob Courant, 78300 POISSY, FRANCE
Single Registration Number (SRN)	FR-MF-000001864

Notified body name	GMED SAS
Notified body number	0459
Directive Certificate number to which this confirmation is made	11826 rev. 9
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26th May 2024
End date of extended validity/transition period	31st December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed devices in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

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- **Directive Certificate** as listed above and covering the listed devices (see attached schedule) was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

  Directive Certificate expired after 20 March 2023 and for which a formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or its substitute and signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS):** A QMS in accordance with Article 10(9) MDR is in place.

- **Device(s) as listed in the attached schedule:**

  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

MANATEC

POISSY (manufacturing site), 13th July 2024.

Signed for and on behalf of the manufacturer:

B.BOSQUET – Company Co-Manager / PRRC

qra@physioflow.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged (contract under definition)	End date of extended validity / transition period
PhysioFlow Enduro	11826 rev. 9	26th May 2024	GMED SAS 0459	GMED SAS 0459	31st December 2028
PhysioFlow Q-Link	11826 rev. 9	26th May 2024	GMED SAS 0459	GMED SAS 0459	31st December 2028