Manufacturer's Declaration

In relation to 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, in particular with respect to

- the validity of certificates issued in accordance with Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and[1]
- 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	Vyaire Medical GmbH
Manufacturer Address and Contact Details	Leibnizstr. 7 97204 Höchberg Germany
Single Registration Number (SRN)	DE-MF-000007090

Notified Body Name	TÜV SÜD Product Service GmbH
Notified Body Number	0123
Directive Certificate Number	G1 071635 0036 Rev. 02
Original Expiry Date	May 26, 2024
End Date of Extended Validity/Transition Period	December 31, 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[2]

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- 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:

➢ **Directive Certificate** as listed above

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessments in respect of the devices covered by the expired certificate or in respect of a device intended to substitute those devices, or

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR, or

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure

☐ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

☒ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made and was submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☒ A QMS in accordance with Article 10(9) MDR is in place.

  ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Devices 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.

Signed for and on behalf of the manufacturer:

Vyaire Medical GmbH

Electronically signed by: Jared Cardon
Reason: I approve this document
Date: Apr 25, 2024 17:23 GMT+2

Jared Cardon
Director QRA / PRRC

Email: Jared.Cardon@vyaire.com

Höchberg, 25.04.2024

Schedule of Devices

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

Identification of the device[3]	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate 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 signed	End date of extended validity / transition period	Substitute Device
Vyntus BODY	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus CPX	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus ECG	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus ONE	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus PNEUMO	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus IOS	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus APS	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Vyntus WALK	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Vyntus SPIRO	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
MicroGard II Filter	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
MicroGard II Filter Kit	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
Mouthpiece	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A
SentrySuite	G1 071635 00 36 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH #0123	TÜV SÜD Product Service GmbH #0123	2028-12-31	N/A