fasciotens
ABDOMINAL WALL SOLUTIONS

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 under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or 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	Fasciotens GmbH
Manufacturer address and contact details	Moltkeplatz 1 45138 Essen Germany Tel: +49 221 177 38 500 Email: info@fasciotens.de
Single Registration Number (SRN) (if available)	DE-MF-000005082

Authorised Representative name (if applicable)	n/a
Authorised Representative address and contact details	n/a
Single Registration Number (SRN) (if available)	n/a

Notified body name (if applicable)	TÜV NORD CERT GmbH See Annex
Notified body number (if applicable)	0044 See Annex
Directive Certificate number(s) to which this confirmation is made (if applicable)	44 235 202109 See Annex
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.May 2024 See Annex
End date of extended validity/transition period	31. December 2028 See Annex

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (and see Annex) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the Annex 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(s)** as listed above or in the Annex

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

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

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

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

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ 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 Annex or its/their substitute(s) 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.

  ☒ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☒ 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 Annex or its/their substitute(s) 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.

➢ **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:

Choose one applicable statement:

☐ 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 Annex 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)**

Choose one applicable statement:

☐ 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.

➢ **Device(s) as listed in the Annex**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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:

Full Company Name	Fasciotens GmbH
Location & Date	Cologne, 22.May.2024
Signature, Print Name, Title	Dr. Gereon Lill, CEO
Contact Details (at least email)	lill@fasciotens.de

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Fasciotens GmbH
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Annex: Schedule of Devices

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

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	fasciotens®Abdomen (A020) fasciotens®Hernia (H010) fasciotens®Pediatric (P010)
Directive Certificate number(s) to which this confirmation is made (if applicable)	Applicable for all above-mentioned devices: 44 235 202109
Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Applicable for all above-mentioned devices: 26.May 2024
Notified Body name and number that issued the Directive Certificate (if applicable)	Applicable for all above-mentioned devices: TÜV NORD CERT GmbH, 0044
Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	Applicable for all above-mentioned devices: DQS Medizinprodukte GmbH, 0297
End date of extended validity / transition period	Applicable for all above-mentioned devices: 31.December 2028
Substitute Device(s) (if applicable)	n/a