TROKAMED GmbH · Kleine Breite 17 · 78187 Geisingen

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/or*[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	TROKAMED GmbH
Manufacturer address and contact details	Kleine Breite 17 78187 Geisingen Germany
Single Registration Number (SRN) (if available)	DE-MF-000005913

Notified body name (if applicable)	DQS Medizinprodukte GmbH
Notified body number (if applicable)	0297
Directive Certificate number(s) to which this confirmation is made (if applicable)	170774582
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-03-31
End date of extended validity/transition period	2028-12-31

[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

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/or*[2]
- the listed **device(s)** 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(s)** as listed above or in the attached schedule

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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.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

[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

schedule 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 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)**

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 attached schedule**

- 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:

TROKAMED GmbH

[redacted]

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
$GD01_Uterusmanipulator 4251303815677SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$GD01ESEO_Uterusmanipulator Zubehör steril einweg 4251303815677SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$GO01_Gynäkologie Zubehör-Operativ 4251303815621RT	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$GO04_Ringapplikatoren 4251303810904R7	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$LO03_Dilatations-Hülsen 4251303815215RC	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$LO08_Elevatoren, Retraktoren 42513038152181FJ	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$LO09_Punktionskanüle, Injektionskanülen 42513038127501FG	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$LO10_Taststäbe 4251303815218RJ	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$LO12_Nähhilfe 4251303812754RS	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$LO13ESR_Morcellator Ventilmodul steril 42513038152602FM	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$ME01_Messer 4251303815226RH	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.

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

$ME02ESR_Schneidmodul, steril 42513038152261FH	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$MO01_Monopolar (HF) 4251303816860SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$MO01ESEO_Monopolarelektroden steril 4251303816860SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$MO04_Lapzangen und -scheren 4251303816860SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$MO06ESEO_Lap Loop 4251303816860SN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$OB01_Trokar, chirurgisch-invasiv 42513038141541F8	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.
$SA01_Basisset Morzellator 4251303816868T6	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$SI01_Schäfte Gynäkologie 4251303810580R3	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$SI03_Schäfte Urologie 42513038152061F7	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$SS01_Saug-Spül-Kanüle 4251303815206RB	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$TH01_Trokarhülsen, sonstige 42513038152601FK	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$UR01_Arbeitselemente Urologie 4251303811497RN	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$VE01_Veress-Kanüle 4251303812750RJ	170774582	2024-03-31	DQS, 0297	DQS, 0297	2028-12-31	n.a.
$ZA02_Zangeninstrumente 42513038156211FW	n.a.	n.a.	n.a.	DQS, 0297	2028-12-31	n.a.