servoprax®

Ihr medizin-technischer Großhandel

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	servoprax GmbH
Manufacturer address and contact details	Am Marienbusch 9 46485 Wesel
Single Registration Number (SRN) (if available)	DE-MF-000007413

Authorised Representative name (if applicable)	N.A.
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule

[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.

Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) 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)

[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

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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.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X 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.

➢ **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.

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Signed for and on behalf of the manufacturer:

Full Company Name	SERVOPRAX GmbH Medizintechnischer Großhandel Postfach 10 08 60 46468 Wesel Am Marienbusch 8 46485 Wesel Telefon 02 81 / 9 52 83-0
Location & Date	Wesel, 07.05.2024
Signature, Print Name, Title	MICHAEL BENNINGHOFF, PRC
Contact Details (at least email)	

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EG-Konformitätserklärung
EC-Declaration of Conformity

Wir / We:
(Name + Adresse der Firma / Name + address of manufacturer)

servoprax GmbH
Am Marienbusch 9
46485 Wesel

erklären in alleiniger Verantwortung, daß das (die) Medizinprodukt(e)
(Name / Artikelnummer:
declare on our own responsibility that the medical device(s)
(name / item-no) :

Art.-Bez.:	**Hygiene Schutzhüllen für Utraschallsonden**
Art.-Nr.:	H5 1330 mit Gleitgel, 32mm Durchmesser, puderfrei
	H5 1280 ohne Gleitgel, 28mm Durchmesser, leicht gepudert
	H5 1320 ohne Gleitgel, 32mm Durchmesser, leicht gepudert
	H5 1340 ohne Gleitgel, 32mm Durchmesser, leicht gepudert
UMDNS:	16-272

allen Anforderungen der Richtlinie 93/42 EWG über Medizinprodukte, geändert durch Richtlinie 2007/47/EG, entsprechen, die anwendbar sind.
Richtlinien-Klassifizierung nach Anhang IX: Klasse IIa, Regel 5.
Die Konformitätsbewertung erfolgt nach dem Verfahren gemäß Anhang VII der RL 93/42/EWG in Verbindung mit dem Verfahren nach Anhang V.
meets all provisions of the Directive 93/42/EEC, changed by the directive 2007/47/EC, which apply to them.
Directive classification according to annex IX: Class IIa, Rule 5.
Conformity assessment procedure according to annex VII in relation to annex V.

Angewandte Normen und andere normative Dokumente:
Applied standards and other normative documents:

Entsprechende Auflistung ist Bestandteil der technischen Dokumentation.
According schedule is part of the appropriate technical documentation.

Die Übereinstimmung des Qualitätssicherungssystems gemäß Anhang V der Richtlinie 93/42/EWG wurde von der u.g. Benannten Stelle bewertet und zertifiziert:
The compliance of the quality assurance system according Annex V of the Directive 93/42/EEC has been assessed and certified by the mentioned below Notified Body:

mdc medical device certification GmbH,
Kriegerstr. 6, 70191 Stuttgart / CE 0483
Zertifikatsnummer / *Certificate No.* D1189400014
Gültig seit / *Validity from:* 2021-05-20
Gültig bis / *expiry date:* 2024-05-26

Die Konformitätserklärung ist gültig bis zur nächsten relevanten Änderung des Produktes, spätestens jedoch bis zum Ablauf des o.g. Anhang V-Zertifikats der servoprax GmbH.
This Declaration of Conformity is valid until: next relevant modification of mentioned product, at the latest with expiry of above mentioned EC Certificate of Conformity Annex V of servoprax GmbH.

Wesel, den 25.05.2021

SERVOPRAX GmbH
Medizintechnischer Großhandel
Postfach 10 08 60 46468 Wesel
Am Marienbusch 9 46485 Wesel
Telefon 02 81 / 9 52 83-0

(Ort und Datum der Ausstellung)
(Place and date of issue)

Michael Benninghoff
(Geschäftsführung / Management)

Hausanschrift: Am Marienbusch 9, 46485 Wesel
Postanschrift: Postfach 100860, 46468 Wesel
Reg.-Gericht: Duisburg HRB 10576
Geschäftsführer: Michael Benninghoff
Ein Unternehmen der Mölders Holding GmbH & Co. KG
www.servoprax.de