Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 095187 0007 Rev. 00

Manufacturer: **Statcorp Medical**
35301 SE Center Street
Snoqualmie WA 98065
USA

Product Category(ies): **Pressure Cuffs for the Infusion of Fluids**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 72155225

Valid from: 2020-04-03
Valid until: 2024-05-26

Date, 2020-04-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

By Royal Charter

Supplementary information to AR120 816589

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

Statcorp Medical
35301 SE Center Street
Snoqualmie WA 98065
USA

Date: 04 December 2024

Changes Approved:

Date	Reference Number	Action
04 December 2024	30266689	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Unifusors. Original NB Certificate Number: G2 095187 0007

Inspiring trust for a more resilient world.

04 December 2024

Statcorp Medical Inc.
35301 SE Center Street
Snoqualmie
Washington
98065
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
G2 095187 0007	AR120 816589	93/42/EEC Annex V	30266689	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Unifusors. Original NB Certificate Number: G2 095187 0007

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl