ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 031695 0040 Rev. 02

Manufacturer:

CREATE MEDIC CO., LTD.
8F, Shin-Yokohama Center Building
2-5-15 Shin Yokohama, Kohoku-ku
Yokohama, Kanagawa
222-0033 JAPAN

SRN Manufacturer - JP-MF-000010849

Authorized Representative:

MDSS GmbH
Schiffgraben 41, 30175 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 031695 0040 Rev. 02

Report No.: JN1994988

Preceding Certificate No.: G10 031695 0040 Rev. 01

Valid from: 2025-06-12
Valid until: 2027-08-24

Date of Initial Issuance: 2022-08-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-06-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 031695 0040 Rev. 02

Classification:	Class IIa
Device Group:	G0301010501 - COLONIC BALLOON CATHETERS, LOW PRESSURE
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	G010201 - SENGSTAKEN TUBES
Intended Purpose:	-/-
Classification:	Class IIb
Device Group:	G02020201 - GASTROSTOMY, TUBES AND SETS
Intended Purpose:	In patients who cannot orally take nutrition, this product is placed through a gastrostomy and used for administration of drugs such as nutrients, food and fluids for a short period of time. It can also be used for gastric decompression. (except for neonates)
Classification:	Class IIb
Device Group:	R0105020101 - TRACHEOSTOMIC CANNULAS, CUFFED, NOT REINFORCED, WITH FIXED FLANGE, AND KITS
Intended Purpose:	Used as the tube to be inserted in the trachea for the purpose of managing the respiratory tract etc. during tracheostomy. (except for neonates)
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2022-08-25	JN1698813	-
01	2025-01-22	JN200350006358	Amended: Editorial change of authorized representative
02	2025-06-12	JN1994988	Supplemented: Device(s)/group of device(s) added

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