Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 104204 0004 Rev. 00

GIÁM ĐỐC

Manufacturer:

Create Biotech Co., Ltd.
No.68, Gong 7th Rd.
Longtan Dist.
32559 Taoyuan City
TAIWAN

Product Category(ies):

Breathing Circuit, Breathing System Filter, Anesthesia Mask, Laryngeal Mask, Tracheal Tube Introducer, Oxygen Mask, Nebulizer, Nasal Cannula, Endotracheal Tube, Manual Resuscitator, Yankauer Suction, Wound Drainage System, Suction Catheter

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.: TW1908001

Valid from: 2019-10-09
Valid until: 2024-05-26

Date, 2019-10-09

Stefan Preiß
Head of Certification/Notified Body

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

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Facility(ies):

Create Biotech Co., Ltd.
No.68, Gong 7th Rd., Longtan Dist., 32559 Taoyuan City, TAIWAN

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