SZUTEST

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1821101

Manufacturer: **GENOSS Co., Ltd.**
Head Office: 1F, Gyeonggi R&DB Center/226, 2F, GSBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Branch Office: 440, Changnyong-daero, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea

Product(s):
1.Sterile Rotary Scalers
2.Sterile Angiographic Syringes
3.Sterile Inflation Device with/without Accessories

Model(s):
1.TN-Brush
2.GENOSS Control Lock Syringe
3.GENOSS Inflator B30, GENOSS Inflator B40, GENOSS Inflator B30 and Accessories, GENOSS Inflator B40 and Accessories

CÔNG TY CỔ PHẦN TRANG THIẾT BỊ Y TẾ TRỌNG TÍN
GIÁM ĐỐC
Trần Doãn Quân

Reference Report No: MM0630-P012-R01, MM0630-P010-R02, MM0630-P013-R01, MM0630-P013-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2023-12-06.

Issue Date: 2018-07-30
Revision No.: 02 Rev.
Revision Date: 2019-03-26

Rukiye BALKAN
Deputy General Manager

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