EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1191937-1

Manufacturer: Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products: Introducer Kits and Guiding Sheaths
Aspects of manufacture concerned with securing and maintaining sterility of
Vascular Compression Cuff

Replaces Approval, Registration No.: HD 60115912 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 234172868-10

Effective date: 2021-05-18

Expiry date: 2024-05-26

Issue date: 2021-05-18

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

S. Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.