



EC declaration of conformity

In accordance with the directive 93/42/EWG on medical products, annex VI

This is a class IIa medical product.

Product : Vacuum Erection Aid System
Type: PRIMUSmed
Manufacturer: tic Medizintechnik GmbH & Co. KG
Endelner Feld 9
D-46286 Dorsten

We at tic Medizintechnik GmbH & Co. KG in our sole responsibility declare that the product *PRIMUSmed* confirms to the relevant requirements of the directive 93/42 EEC on medical product.

The conformity declared here with revision level A7 is valid for all *PRIMUSmed* that has been placed on the market for the first time since 6th June 2019. The manufacturer manages and writes the conformance *PRIMUSmed* in an electronic file. The conformity declared here is only valid in conjunction with this list for the devices specified therein and until the product has been changed and / or the date of expiry of the certificate (s) issued by the notified body. Identification is via the serial number.

Applied norms: acc. to harmonized norms of RL 93/42/EWG on medical devices



--- Notified body: BSI Group, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam

Dorsten, 6th June 2019

Place / Date


Signature Management