

Declaration of Conformity Medical Probe Covers 2020.06.17



1. Declaration of Conformity

We,

Ritex GmbH
Gustav-Winkler Straße 50
33699 Bielefeld
Germany

declare in sole responsibility that our medical devices

Medical Probe Covers

comply to the relevant provisions of the directive 93/42/EEC for the production period from 2020-05-26 to 2021-05-25. The validity of this declaration expires in case of an issue of a revised declaration of conformity after a product change.

Bielefeld, June 17th, 2020

Dr. J. Drögemeier
(Quality management)

2. Classification

The probe covers manufactured at Ritex are to be assigned into risk class I according to rule 5, annex IX, of directive 93/42/EEC.

3. Notified Body

Not applicable

4. Conformity Assessment Procedure

Procedure of EC declaration of conformity according to annex VII of the directive 93/42/EEC

5. Revision Status

2020.06.17/b