

Declaration of Conformity Medical Probe Covers 2021.05.26



1. Declaration of Conformity

We,

Ritex GmbH
Gustav-Winkler Straße 50
D-33699 Bielefeld
Germany

declare in sole responsibility that our medical devices

Medical Probe Covers

comply to the relevant provisions of the regulation (EU) 2017/745 for the production period from 2021-05-26 to 2022-05-25. The validity of this declaration expires in case of an issue of a revised declaration of conformity after a product change..

Bielefeld, May 26th 2021

S. Bodemeier
(Responsible Person)

2. Classification

The listed probe covers are to be assigned into risk class I according to rule 5, annex VII of the regulation (EU) 2017/745.

3. Intended Use

Medical probe covers for vaginal/ rectal probes to reduce the risk of transmission of infections

4. Notified Body and Certificate ID

n.a.

5. Conformity Assessment Procedure

Procedure of EU declaration of conformity acc, to art. 19 of the regulation (EU) 2017/745

6. Used Harmonised Standards or Common Specifications

n.a.

7. Basic UDI-DI:

406629406NW

8. Revision Status

2021.05.26/d