

# Declaration of Conformity Medical Probe Covers 2023.05.26

## 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 2023-05-26 to 2024-05-25. The validity of this declaration expires in case of an issue of a revised declaration of conformity after a product change.

Bielefeld, May 26th 2023

  
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

2023.05.26/e