Declaration of Conformity Medical Probe Covers 2025.03.11

1. Declaration of Conformity

We,

Ritex GmbH
Gustav-Winkler Straße 50
D-33699 Bielefeld
Germany
SRN: DE-MF-000005708

declare in sole responsibility that our medical devices

Probe Covers

Subbrands: Sondosecur 28 mm and Sondosecur 34 mm

comply to the relevant provisions of the regulation (EU) 2017/745 for the production period from 2025-03-11 on. The validity of this declaration expires in case of an issue of a revised declaration of conformity after a product change.

Bielefeld, March 11th 2025

S. Bodemeier
(Person Responsible for Regulatory Compliance)

2. Classification

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

3. Intended Purpose

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

4. Notified Body and Certificate ID

n.a.

5. Conformity Assessment Procedure

Procedure of Declaration of Confomity to MDR, CE marking without Notified Body

6. Used Harmonised Standards or Common Specifications

EN ISO 4074

7. Basic UDI-DI:

406629406NW

8. Revision Status

250511/g