

## Declaration of Conformity Condoms 2021.05.25



### 1. Declaration of Conformity

We,

Ritex GmbH  
Gustav-Winkler Straße 50  
33699 Bielefeld  
Germany

declare in sole responsibility that our medical devices

#### Condoms

comply to the relevant provisions of the directive 93/42/EEC for the production period from 2021-05-25 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 25th 2021

S. Bodemeier  
(Regulatory Affairs)

### 2. Classification

All condoms manufactured at Ritex are to be assigned into risk class IIb according to rule 14, annex IX, of directive 93/42/EEC.

### 3. Notified Body

Identification number: 0297  
DQS Medizinprodukte GmbH – Deutsche Gesellschaft zur Zertifizierung von Managementsystemen  
August-Schanz-Str. 21, 60433 Frankfurt am Main, Germany

### 4. Conformity Assessment Procedure

Procedure of EC declaration of conformity (full quality assurance system) according to annex II – without section 4 – of the directive 93/42/EEC

### 5. Revision Status

2021.05.25/b