

Declaration of Conformity Condoms 2020.02.20

1. Declaration of Conformity

We,

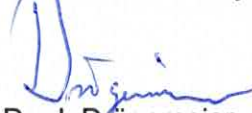
Ritex GmbH
Gustav-Winkler Straße 50
33699 Bielefeld
Germany

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 2020-01-01 to 2022-02-19. The validity of this declaration expires in case of an issue of a revised declaration of conformity after a product change.

Bielefeld, February 20th 2020



Dr. J. Drögemeier
(Quality Management)

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

2020.02.20/a