

Declaration of Conformity Condoms 2021.05.25**1. Declaration of Conformity**

We,

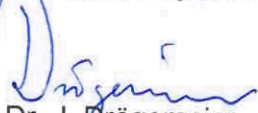
MedDevice GmbH
Gustav-Winkler Straße 50
D-33699 Bielefeld

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



Dr. J. Drögemeier
(Quality management)

2. Classification

All condoms manufactured at MedDevice 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