

Declaration of Conformity Lubricant Class IIa 2021.05.25



1. Declaration of Conformity

We,

Ritex GmbH
Gustav-Winkler Straße 50
33699 Bielefeld
Germany

declare in sole responsibility that our medical device

Ritex Gel+

complies 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.

Bielefeld, May 25th, 2021

S. Bodemeier
(Regulatory Affairs)

2. Classification

The listed lubricants manufactured at Ritex are to be assigned into risk class IIa according to rule 5, 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