Declaration of Conformity Lubricant Class I 2020.02.26

1. Declaration of Conformity

We,

Ritex GmbH
Gustav-Winkler Straße 50
33699 Bielefeld
Germany

declare in sole responsibility that our medical devices

Ritex HYDRO Sensitiv Gel, Ritex BIO Gleitgel and Ritex KINDERWUNSCH Gleitmittel (Lubricants Class I)

comply to the relevant provisions of the directive 93/42/EEC for the production period from 2020-01-01 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, April 7th, 2022

Dr. J. Drögemeier
(Quality management)

2. Classification

The listed lubricants manufactured at Ritex are to be assigned into risk class I according to rule 5, annex IX, of directive 93/42/EEC.

3. Notified Body

Not applicable

4. Conformity Assessment Procedure

Procedure of EC declaration of conformity according to annex VII of the directive 93/42/EEC

5. Revision Status

2020.02.26/a corr. 2022.04.08