

EU Declaration of Conformity RND

DoC nr: 2020-000XX



We:

Company name:	Distrelec Group AG
Postal address:	Enterprise Hub, 7th Floor, 2 St Peter's Square
Postcode and City:	Manchester, M2 3AA
E-Mail address	rnd@distrelec.com
Hereby declare that:	

RND ARTICLE NUMBER	RND PRODUCT DESCRIPTION
RND 600-00269	Disposable non-sterile nitrile glove, size S
RND 600-00270	Disposable non sterile nitrile glove, size M
RND 600-00271	Disposable non sterile nitrile glove, size L
RND 600-00272	Disposable non sterile nitrile glove, size XL

Has been manufactured in conformity to the following community Directives/Regulations and Standards:

Council Directive 93/42 / EEC of 14 June 1993 concerning medical devices:

Class I according to directive 93/42/EWG Appendix IX; Rule 1

Applied standards:

EN ISO 13485:2016 Medical devices – Quality management systems
Requirements for regulatory purposes (ISO 13485:2016)

Chosen conformity procedures:

Directive 93/42/EEC Appendix VII

Validity of the Declaration of Conformity:- 31/03/2024

DISTRELEC

Signed for and on behalf of:

David Connelly

Senior Quality & Legislation Manager

Date 13/11/2020