

EU Declaration of Conformity RND

DoC nr: 2020-00061



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 600-00264	Latex powder free disposable gloves S
RND 600-00265	Latex powder free disposable gloves M
RND 600-00266	Latex powder free disposable gloves L
RND 600-00267	Latex powder free disposable gloves 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 directive 93/42/EEG 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:

According the Directive 93/42/EEC Appendix VII

Validity of the Declaration of Conformity:

2024-03-31

DISTRELEC

Signed for and on behalf of:

David Connelly

Date 03/11/2020

Senior Quality & Legislation Manager