

Declaration of Conformity

Powder Free Polymer Coated Latex Examination Gloves

Declaration of conformity:

With this Declaration of conformity, we declare that the abovementioned product conforms to the requirements laid down in Medical Device Directive 93/42/EEC and the Regulation 2016/425 for Personal Protective Equipment

Identification:

E2TD - Specification Latex Examination Gloves Powder Free Polymer Coated Non Sterile.
Brand: Distributed in Switzerland by Cosanum AG, 8952 Schlieren, under the following references
Exam Gloves cosaLine Latex Satin white powderfree
XS 171003200
S 171003201
M 171003202
L 171003203
XL 171003204

Normative References:

EN 455 part 1, 2, 3 & 4
EN 420
Reference is made to EU Type-examination Certificate 2777/11630-01/E00-00

Conformity assessment:

Following the provision in conformity assessment procedure listed in Annex VII of Medical Device Directive 93/42/EEC, as amended by the Council directive 2007/47/EC
And
Following the conformity assessment procedure listed in Annex V (Module B) of Regulation 2016/425 for Personal Protective Equipment

Category:

Class I Medical Device
CAT III Personal Protective Equipment

Date:

2019.05.31


MediPart ApS
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