

EU Declaration of Conformity

Manufacturer: Medasept S.A.; ul. Forteczna 19; 61-362 Poznań

We declare under our sole responsibility that the following latex examination gloves powdered, non-sterile

Brand:

medaSEPT latex

Size:

XS, S, M, L, XL

Classified as the medical device of Class I, according to Annex IX of the Council Directive 93/42/EEC.

The list of used standards compatible with the requirements of the Council Directive 93/42/EEC:

EN 15223

EN ISO 14971

EN 455-2

EN 1041

EN ISO 13485

EN 455-3

EN ISO:9001

EN 455-1

EN 455-4

Medical device conformity assessment procedure: Annex I + VII of the Council Directive 93/42/EEC amended by the Directive 2007/47/EC.

and

as a Category I- meet all provisions with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Protective Personal Equipment and repealing resolution of the Council Directive 89/686/EEC and compatible European standards:

EN 420:2003+A1:2009

Poznań, 01.03.2021

Signature on behalf of the manufacturer

Medasept Spółka Akcyjna

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Dyrektor ds. Zakupów i Produktów

Jowita Boryda-Czyrnańska
Purchasing & Product Director