



Declaration of Conformity

Manufacturer: Medasept Sp. z o.o.; ul. Forteczna 19; 61-362 Poznań

We declare under our sole responsibility that the following latex examination gloves

Brand:

medaSEPT latex PF

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:

<i>EN 15223</i>	<i>EN ISO 14971</i>	<i>EN 455-2</i>
<i>EN 1041</i>	<i>EN ISO 13485</i>	<i>EN 455-3</i>
<i>EN ISO:9001</i>	<i>EN 455-1</i>	<i>EN 455-4</i>

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, 08.09.2020

Signature on behalf of the manufacturer

MEDASEPT
Spółka z ograniczoną odpowiedzialnością
61-362 Poznań, Forteczna 19
NIP 7822557229 REGON 302347543

Dyrektor ds. Zakupów i Produktów
Jowita Boryca-Szymańska
Purchasing & Product Director