



Declaration of Conformity

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

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

Brand:

medaSEPT® vinyl blue

Size:

XS, S, M, L, XL

Classified as the medical device of Class I, Rule 4 according to Ordinance of Minister of Health 5.11.2010 about way of classification medical products, meet all provisions of the Act of 20.05.2010 about Medical Products.

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

EN 15223-1:2012

EN ISO 14971:2012

EN 455-2+A1:2011

EN 1041:2008

EN ISO 13485:2012

EN 455-3:2006

EN ISO:9001

EN 455-1:2000

EN 455-4:2009

Conformity assessment procedure: Annex I + VII of Minister of Health Ordinance of 12.01.2011 about provisions and procedures of conformity assessment medical products.

and

as a Category I- for minimal risk, meet all provisions of the Council Directive 89/686/EEC which apply to them. The list of adopted compatible standards:

EN 374-1:2003 excluding clause 5.3.2.

EN 374-2:2003

EN 420:2003+A1:2009

Poznań, dnia 20.12.2017

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
Jawita Boryca-Szymańska
Purchasing & Product Director