

DECLARATION OF CONFORMITY WE

Manufacturer: MODUS S.A. Przedsiębiorstwo Odzieżowe S.A.

Address: ul. Karola Szajnochy 11, 85-738 Bydgoszcz, POLAND

Product name: disposable apron with press studs

Model: 202010, 202011

classified as **class I** according to rule 1 according to the regulation of the Minister of Health of 5 November 2010 on the classification of medical devices (Journal of Laws No. 215 of 2010, item 1416)

complies with the essential requirements of Council Directive 93/42 / EEC implemented into the legal system of the Republic of Poland by the Act of May 20, 2010 on medical devices (Journal of Laws No. 107 of 2010, item 679, as amended), harmonized standards:

EN 11737-1:2018	[PN-EN 13737-1:2018] Determination of the population of microorganisms on products - Microbiological purity.
EN ISO 9073-10:2006	[PN-EN ISO 9073-10:2006] Release of textile dust and other particles when dry.
EN ISO 22610:2007	[PN-EN 22610:2007] Surgical drapes, gowns and clothing for operating theaters, used as medical devices for patients, medical staff and equipment - Method to determine wet resistance to bacteria.
1907/2006	[PN-EN 16711-1:2016-01] REACH – Registration Evaluation Authorisation Restriction of Chemicals). European Union Regulation of June 1, 2007. Chemical substances in industrial processes.
EN ISO 14971:2012	[PN-EN ISO 14971:2012] Medical products. Application of risk management to medical devices.

The product meets the essential requirements of the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures for medical devices (Journal of Laws of 2016, item 211) and the Council Directive 93/42 / EEC (93/42 / EEC), as amended.

Conformity assessment was carried out in accordance with the requirements of Council Directive 93/42 / EEC as amended by Council and Parliament Directive 2007/47 / EC, Annex VII.

This declaration of product conformity is issued under the sole responsibility of the manufacturer.

Place: Bydgoszcz, 01.10.2020r

Signature:

PREZES ZARZADU
"MODUS" S.A.
Dyrektor Generalny

Marek Ulewicz

"MODUS"
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