



EU DECLARATION OF CONFORMITY

Manufacturer (Address)	OPTIBLOK Sp. z o.o. ul. Igańska 20 / Uż/3 04-087 Warszawa NIP 1132826654	Single registration number (SRN)	PL-MF-000003272
Device name	Spectacle frame for corrective lenses		
Basic UDI-DI	5904999700017	EMDN code	Q02100203
Risk class	Class 1	Classification rule	Rule I
Conformity assessment	Based on Annexes II, III of Regulation (EU) 2017/745.		
Brands	BELUTTI; CARLO AUBERA; CORIDA EMOTION; EXTETE; IMPRESION; FIESTA; NAVYJACK; MACHO; TRENDY; OLAF CARRÉN; CROWN.		
Intended use	Spectacle frames are an integral part of the medical device - corrective spectacles designed to correct the patient's refractive errors. In combination with the appropriate lenses, frames optimise the treatment process of visual impairment, prevent its progression and compensate for the resulting visual impairment.		
I hereby declare on behalf of the Manufacturer - OPTIBLOK Sp. z o. o. and under its sole responsibility that the medical device listed above meets the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.			
Standards applied: PN-EN ISO 13485:2016-04; PN-EN ISO 14971:2019; PN-EN ISO 20417:2021-10 PN-EN ISO 15223-1:2022-01; PN-EN ISO 12870:2018-06; PN-EN ISO 10993-1:2021 PN-EN 62366-1:2015-07E			
<p>OPTIBLOK Sp. z o.o. 04-087 Warszawa, ul. Igańska 20/Uż.3 adres do korespondencji: 04-239 Warszawa, ul. Młodnicka 39 A NIP 113-282-66-54 REGON 142811872 tel. 22-870 23 31 fax 22-879 88 03</p> <p>(Company stamp)</p>		  <p>(President of the Management Board - Jolanta Krasnodębska / Signature)</p>	