VERDENT

CE Declaration of conformity for the device:

Non- woven medical masks, 3-layer , disposable

VERDENT LTD

38/52 Czestochowska street

93-121 Lodz, POLAND

Declares that :

Non- woven medical masks, 3-layer, disposable type II R

LOT No: QTY

comply with the requirements of the Act of 20 May 2010 on medical devices (Dz.u.2010 No. 107 Pos. 679) and the Minister of Health of 17 February 2016 on the essential requirements and conformity assessment procedures for medical devices (Dz.U.2016 Poz.211).
A medical device is classified as Class I rule 1, according to the Minister of Health dated. 5 November 2010 on the method of classifying medical devices (Dz.U.2010 Nr 215 item 1416) .

The product meets the requirements of the Council Directive of 14 June 1993 93/42/EWG concerning medical devices and 2007/47/EWG,
and that it was manufactured in a certified Quality Management System is compatible with the following standards:

PN-EN ISO 9001:2015-10 ***PN-EN ISO 13485:2016-04***

PN-EN ISO 14971:2012 ***PN-EN 14683+AC:2019-09***

The declaration shall be made exclusively liable to the manufacturer.

Date and place, Lodz 23.07.2020

.....
Michal Wlodarczyk
President

VERDENT Sp. z o.o.
ul. Częstochowska 38/52, 93-121 Łódź
tel.+48 42 288-40-51 (52)
NIP: 728-279-03-98, Regon:101451470
BDO:000068254