

Declaration of Conformity According to Directive no 93/42/EEC

We, **PT. Medisafe Technologies,**
Jl. Batang Kuis Gg. Tambak Rejo / PSR IX, Desa/Kelurahan Buntu Badimbar,
Kec. Tanjung Morawa. Kab. Deli Serdang 20362.

Declare with sole responsibility, that our product/s:

<u>UMDNS Code</u>	<u>UMDNS Description</u>	<u>Classification</u>
11-883	Sterile Surgical Polychloroprene Gloves	Class IIa /MDD

Description of Goods : Powder Free Polychloroprene Surgical Gloves
Product Code : CR-SG-98, CR-SG-119, CR-SG-130, CR-SG-135 & CR-SG-140
Brand : Chlorosense Micro, Chlorosense, Chlorosense Optima, Chlorosense Freedom
& Neotex Purederma

Object of the declaration:

Risk class of the device in accordance with the rules set out in Rule 6

- **meet, the essential requirements of Council Directive 93/42/EEC & EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, EN 455-4:2009 Standard**

European representative : THEO MANUFACTURING BV
Sleperweg 44, 6222 NK, Maastricht, the Netherlands
info@theomanufacturing.com

Notified Body : **TUV NORD (CE 0044)**

CE Registration number : 44 235 117840



Peggy Supratman

Sr. Manager QA, RA & DC

Signed this day 30 April 2021