KRONOSAN
READY HEALTHCARE SERVICES

Cotignola, November 12th, 2021

EU Declaration of Conformity

According to Medical Device Regulation 2017/745

and PPE Regulation (EU) 2016/425

We, manufacturer,

Kronosan S.r.l.
Via Vecchia Corriera, 11
48033 Cotignola (RA), Italy
Phone +39 0545 79111

herewith declare, that the following Examination Gloves

KRONOSAN Powder-Free Stretch Vinyl Gloves
(Article code: S -P13005150; M -P13005151; l -P13005152; XL -P13005153)

Basic UDI-DI : 805071465T0102020159

comply with the requirements of PPE (EU) 2016/425 and harmonized standards EN420:2003+Al:2009, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 374-2: 2019, EN 16523-1:2015+A1:2018, EN 374-4:2019.

The product is a medical device in accordance with the requirement of the Medical Device Regulation (EU) 2017/745, under Class I Medical Device set out in Rule number 5 of Annex VIII, and a PPE Category III-Complex in accordance with attachment I of the regulation and the notified body BSI Group The Netherlands (Number: 2797) performed the EU type-examination certificate number is CE 755080 (Module B) and assessment procedure Module C2 under surveillance of the EU type-examination certificate CE 630603, issued by the notified body:

Notified Body number: 2797
BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam Netherlands

Date: 2021.11.12

For and on behalf of
Kronosan S.r.l.
Amministratore Delegato
Ing. Andrea Masina