

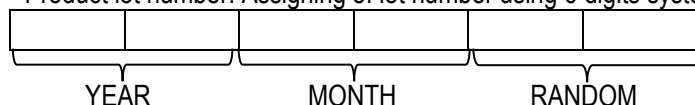
# ROMED HOLLAND

## Declaration of Conformity

|  |   |   |
|--|---|---|
| Manufacturer                                     | Van Oostveen Medical BV<br>Herenweg 269<br>3648 CH Wilnis<br>Netherlands            | Tel: 0031 297 282101<br>Fax: 0031 297 288316<br>E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a><br>Website: <a href="http://www.romed.nl">www.romed.nl</a> |
| Notified Body                                    | TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany                                  |   |
| Notified Body ID Number                          | 0044  |   |
| Validity of this Declaration of Conformity until | 11 March 2024   |   |
| Product  | Latex surgical gloves, sterile, powderfree<br>Ref: SGPF-006/065/007/075/008/085/009 |   |
| Brand  | ROMED   |   |
| Classification (MDD, Annex IX)                   | IIa   |   |
| Classification (PPE, article 19)                 | CAT I   |   |
| UMDNS  | 11883   |   |

We, with sole responsibility in drawing up this Declaration of Conformity, declare that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

Product lot number: Assigning of lot number using 6 digits system as below:



### DIRECTIVES

#### General applicable directives and regulations

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) according to Annex II as amended by council directive MDD 2007/47/EC REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

#### Applicable standards

EN 455-1:2020, 2:2015, 3:2015, 4:2009, ISO 10282:2014, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 03 November 2022



M.J. van Oostveen  
Managing Director