

ROMED HOLLAND

Declaration of Conformity

| | |
|--|--|
| Manufacturer | Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website : www.romed.nl |
| 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 | Hypodermic syringes sterile for single use Ref: SYR-2/5/10/20ml, 2-part Ref: 3SYR-3/5/10/20/50ml, 3-part Ref: 3S-50-LL / SYR60ML-LT / 3SYR100ML-LT, 3SYR200ML-LT |
| Brand | ROMED |
| Classification (MDD, Annex IX) | I (sterile) |
| UMDNS | 13929 |

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.

DIRECTIVES

General applicable directives

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

Applicable standards

EN ISO 7886-1:2018, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021(cor 2021-12).

Wilnis, The Netherlands, 18 October 2022



M.J. van Oostveen
Managing Director