

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands Tel: 31-297-282 101 Fax 31-297-288316 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	Urine Bags, 2 Litres, with non-return valve, sterile Bottom outlet, Ref: UB2LN RV-ST Cross bottom outlet, Ref: UB2LSTTV
Brand	ROMED
Classification (MDD, Annex IX)	I (sterile)
UMDMS	14298

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 8669-2:1996, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN 556-1:2001, 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