

21ROMED 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, Langemarckstrasse 20, 45141 Essen, Germany
Notified Body ID Number	0044
Validity of this Declaration of Conformity until	29 July 2019
Product	Intravenous Catheters with Injection Port Ref: IVCATH-14G/16G/18G/20G/22G/24G
Brand	ROMED
Classification (MDD, Annex IX)	Ila

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

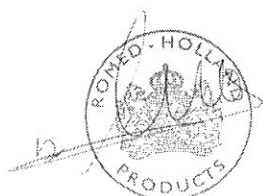
General applicable directives

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

Standards

Harmonised Standards (published in the Official Journal of the European Communities) applicable to this product are: EN ISO 10555-5:2013, EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 11607-1:2014, EN ISO 15223-1:2012, EN 1041:2008

Wilnis, The Netherlands, 20 November 2020



M.J. van Oostveen
Managing Director

