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, Langemarckstrasse 20, 45141 Essen, Germany
Notified Body ID Number	0044
Validity of this Declaration of Conformity until	11 March 2024
Product	Foley balloon catheters 2-way and 3-way Paediatric Foley balloon catheters Latex REF: CATH-(size) / 3CATH-(size)
Brand	ROMED
Classification (MDD, Annex IX)	**IIa**
UMDNS	**10720**

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 1616:1997, EN ISO 20696:2018, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN 556-1:2001, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

Wilnis, The Netherlands, 10 January 2022

M.J. van Oostveen
Managing Director