

# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	<b>Van Oostveen Medical BV</b> <b>Herenweg 269</b> <b>3648 CH Wilnis</b> <b>Netherlands</b> <b>Tel: 0031 297 282101</b> <b>Fax: 0031 297 288316</b> <b>e-mail: <a href="mailto:info@romed.nl">info@romed.nl</a></b> <b>website : <a href="http://www.romed.nl">www.romed.nl</a></b>
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 2016
Product	Male condoms Ref : CON-500R/ CON-3P40 CON-FLA, CON-THN, CON-STR, CON-COL, CON-TEX
Brand	ROMED
Classification (MDD, Annex IX, Rule 14)	<b>IIb</b>

We, with sole responsibility in drawing up this conformity certificate, 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/EEC.

**Standards**

Harmonised Standards (published in the Official Journal of the European Communities) applicable to this product are: ISO 4074:2002.

Wilnis, The Netherlands, 7 October 2022



M.J. van Oostveen  
Managing Director