

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	Thermometers, Forehead, Digital, Infrared Ref: THERM-IR
Brand	ROMED
Classification (MDD, Annex IX)	Ila
UMDNS	14032

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 are retained under the premises of the manufacturer and notified body.

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 80601-2-56:2017, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

Wilnis, The Netherlands, 07 June 2021



M.J. van Oostveen
Managing Director