

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
Validity of this Declaration of Conformity until	11 March 2024
Product	Scalpel handles for surgical blades Ref: HANDLE-3/4
Brand	ROMED
Classification (MDD, Annex IX)	I
UMDNS	12235

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

ISO 7740:1985, EN 27740:1992, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1 :2013.

Wilnis, The Netherlands, 22 March 2022



M.J. van Oostveen
Managing Director