

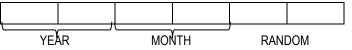
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 E-mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	Website : www.romed.nl
SRN	NL-MF-000003481	
Product	Bouffant Caps (white / blue / green)	
	Ref: BOCAP-W/-B/-G	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CATI	
UMDNS	13882	
GMDN	32297	
Basic UDI-DI	871720243MDIBCPEDN0000148	

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, Regulations and Standards. All supporting documentation is retained under the premises of the manufacturer.

Product lot number: Assigning of lot number using 6 digits system as below:



General applicable directives and regulations

REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Applicable standards

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021 (cor. 2021-12). No EU common specifications are applicable.

Wilnis, The Netherlands, 03 November 2022 Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen Managing Director

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