



AGENTIA MEDICAMENTULUI
SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc	Model	Nr. catalog	Tara	Producator	Reprezentant	Ordin	Data
					Olanda		Î.M. BECOR S.R.L.		17.11.2015
DM000003875	SET STERIL PENTRU PERFUZII	ROMED@	21G 1 1/2" 145 CM	IVFD400	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003871	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 18G 1,2 X 45 MM, ≥ 75 ML/MIN	IVCATH-18	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003873	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 22G 0,8 X 25 MM, ≥ 25 ML/MIN	IVCATH-22	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003876	SET STERIL PENTRU PERFUZII	ROMED@	21G 1 1/2", 180 CM, Y TUBE	IVFD400Y	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003869	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 14G 2 X 45 MM, ≥ 250 ML/MIN	IVCATH-14	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003874	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 24G 0,7 X 20 MM, ≥ 15 ML/MIN	IVCATH-24	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003872	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 20G 1 X 32 MM, ≥ 54 ML/MIN	IVCATH-20	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015
DM000003870	CATETER INTRAVENOS	ROMED@	CU VALVĂ INJECTOARE, 16G 1,6 X 45 MM, ≥ 150 ML/MIN	IVCATH-16	Olanda	VAN OOSTVEEN MEDICAL B.V.	Î.M. BECOR S.R.L.	A07,PS-01.Rg04-275	17-11-2015

☒ [CerereDeIntrsgModifDM.Reprezentantului,DisplayName] Равно 'Î.M. BECOR S.R.L.' И [Data] Равно '17-11-2015'

ОЧИСТИТЬ



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	29 July 2016
Product	I.V. Catheters with Injection Port Ref: IVCATH14 16 18 20 22 24
Brand	ROMED
Classification (MDD, Annex IX)	Ila

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/EEC.

Standards

Harmonised Standards (published in the Official Journal of the European Communities) applicable to this product are: EN-ISO 10555-5: 1996

Wilnis, The Netherlands, 1 June 2021



M.J. van Oostveen
Managing Director

