

m.Chisinau; Calea Orheiului 111/5
tel. 406299; fax. 406271
tel.GSM 069140864
orele de lucru: 8.00 – 17.00

г.Кишинэу ; Калеа Орхейулуй 111/5
тел. 406299; факс. 406271
моб тел, 069140864.
рабочее время: 8.00 – 17.00

Către Agenția Medicamentului
și Dispozitivelor Medicale
Secția management și supraveghere dispozitive medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. din

Solicitantul ÎM „Becor”SR, cu sediul str. Calea Orheiului 111/5. mun. Chișinău.
(adresa)

tel./fax: 022406290, e-mail v.luca@becor.md

solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și
tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Prezervative Romed

Producător: **Van Oostveen Medical BV, Olanda**

Se anexează următoarele acte:

1. Certificatul CE
2. Declarația de Conformitate
3. Declarație pe proprie răspundere
4. Pover of attorney

Data 02.10.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

ANLAGE / ANNEX

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Annex 1, page 5 of 5

Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse IIa
Products of class IIa

Thermometer, elektronisch
Thermometers, Electronic

Dreiwegehahn
Three-way stopcock

UMDNS

14-032

13-803

Produkte der Klasse IIb
Products of class IIb

Kondome, männlich
Condoms, Male

UMDNS

18-080

Bericht Nr. / Report No. 3523 7664



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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Produkte der Klasse IIa
Products of class IIa

UMDNS

Intravenöses Infusionsbesteck, allgemeine Verwendung
Intravenous Administration Sets, General Purpose

12-157

Katheter, intravenös, peripher
Catheters, Intravenous, Peripheral

10-727

Intravenöses Infusionsbesteck Kopfhautvene
Intravenous Administration Sets, Scalp Vein

17-825

Nadeln, hypodermisch
Needles hypodermic

12-745

Verband, nichthaftend
Dressing, Nonadherent

11-325

Spritze, subkutan
Syringe, hypodermic

13-940

Spritze, Tuberkulin
Syringes, Tuberculin

13-945

Spritze, Insulin
Syringes, Insulin

13-941

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Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse IIa
Products of class IIa

UMDNS

Klinge, Messer
Blades, Knife

12-234

Messer, Skalpell
Knives, Scalpel

12-252

Bluttransfusionsbesteck
Blood Administration Set

10-421

Lanzette, Blut
Lancets, Blood

10-440

Blutdruckmeßgerät, elektronisch
Sphygmomanometers, Electronic

16-157

Endotracheal Tubus
Endotracheal tubes

14-085

Katheter, Harnwege, Foley
Catheters, Urinary, Foley

10-720

Handschuhe, chirurgisch
Gloves, Surgical

11-883

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Produkte der Klasse Is
Products of class Is

UMDNS

Spritzen 2- und 3-teilig
Syringes 2- and 3-part

13-929

Harnauffangbeutel
Urinary Collection Bags

14-298

Harnauffangbeutel, Säugling
Urinary Collection Bags, Infant

16-782

Untersuchungshandschuhe, steril
Examination gloves sterile

11-882

Tropfer, Medikamente
Dropper, Medicine

12-506

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.

Note: For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

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Gültigkeit / Validity
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Certification body for medical devices

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

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Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse Im
Products of class Im

UMDNS

Thermometer, Quecksilber frei
Thermometer, Mercury free

14-028

Blutdruckmeßgerät, aneroid
Sphygmomanometers, Aneroid

16-156

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

Note: For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

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Gültigkeit / Validity
von / from 2019-03-12
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Essen, 2019-03-12

TÜV NORD CERT GmbH

Langemarckstraße 20

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medical@tuev-nord.de

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EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Van Oostveen Medical B. V.

Herenweg 269
3648 CH Wilnis
The Netherlands

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Skalpellklingen, Skalpelln, Bluttransfusionssets, Blutlanzetten, elektronische Blutdruckmessgeräte, Kondome, Trachealtuben, Foley Ballon Katheter, chirurgische Handschuhe, Infusionssets, Intravenöse Katheter, Nadeln, Paraffingaze, Intravenöse Infusionsbestecke Kopfhautvenen, Spritzen komplett mit Kanüle, Tuberkulinspritzen, Insulinspritzen, digitale Thermometer, 3-Wegehähne, Aneroide Blutdruckmessgeräte, Thermometer, Untersuchungshandschuhe, Spritzen, Urinbeutel, Tropfer für Medikamente.

Blades, Scalpels, Blood Administration Sets, Blood Lancets, Electronic Sphygmomanometers, Condoms, Tracheal Tubes, Foley Balloon Catheters, Surgical Gloves, Infusion Sets, Intravenous Catheters, Needles, Paraffin Gauze, Scalp Vein Infusion Sets, Syringes complete with Needle, Tuberculin Syringes, Insulin Syringes, Digital Thermometers, Three Way Stopcocks, Aneroid Sphygmomanometers, Thermometers, Examination Gloves, Syringes, Urine Bags, Droppers for Medicine.

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 04 232 041335
Bericht Nr. / Report No. 3523 7665



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
bis / until 2024-03-11
Edition 4

Essen, 2019-03-12

TÜV NORD CERT GmbH

Langemarckstraße 20

45141 Essen

www.tuev-nord-cert.de

medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



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ZLG-BS-236.10.16



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	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)	IIb

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, 22 June 2023



M.J. van Oostveen
Managing Director



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tel. 406299; fax. 406271
tel.GSM 069140864
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моб тел, 069140864.
рабочее время: 8.00 – 17.00

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: ÎM „Becor” SRL,
cu sediul str. Calea Orheiului 111/5., mun. Chișinău,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Prezervative Romed

Producător: **Van Oostveen Medical BV, Olanda**

Sunt autentice și corespund realității.

Farmacist. Luca Victoria
Numele, prenumele și funcția

Data 02.10.2023

Semnătura



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

POWER OF ATTORNEY

We, **Van Oostveen Medical B.V.**, a company organized and existing under the laws of The Netherlands, with registered head office at Herenweg 269, 3648 CH WILNIS, The Netherlands, (hereinafter, the "Manufacturer") hereby appoint:

Mrs. Luca Victoria, Specialist in the Department of Certification and Registration within **Becor Company** (Authorized Representative) within juridical address: Calea Orheiului Street 111/5, 2020 CHISINAU, Republic of Moldova, passport no. B03007217, (hereinafter, the "Representative"),

to take any and all necessary and appropriate actions in connection with the registration of the products manufactured by the Manufacturer, to make and to sign any and all documents, including but not limited to, contracts, applications, statements and their amendments; and to execute any other actions in connection with the products registration all in accordance with the Sales and Delivery and Conditions of the Manufacturer

The Representative shall not assign its authority under this Power of Attorney to any third party, without Manufacturer's prior written consent.

This Power of Attorney shall be effective from the date indicated below and shall remain in force for a period of 2 years thereafter and may be revoked by the Manufacturer at any time.

This Power of Attorney has been executed on September 22, 2023.

Sincerely,

For and on behalf of Van Oostveen Medical B.V.


M.J. van Oostveen,
Managing Director

VAN OOSTVEEN MEDICAL B.V.

Herenweg 269 - 3648 CH WILNIS

The Netherlands

Tel.: +31 297 282101

Fax.: +31 297 288316

info@romed.nl

www.romed.nl



Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod UMDNS
1		Prezervative	Romed	CON3P40 obișnuite, unicolore	18-080
2		Prezervative	Romed	CON-500R - obișnuite, unicolore	18-080
3		Prezervative	Romed	CON-COL - diferite culori	18-080
4		Prezervative	Romed	CON-THN - extra subțiri	18-080
5		Prezervative	Romed	CON-FLA - diferite arome	18-080
6		Prezervative	Romed	CON-TEX - texturate	18-080
7		Prezervative	Romed	CON-STR - extra forte	18-080