PROCURĂ

31.10.2023 mun.Chișinău

Prin prezenta procură, **ORTONET SRL**., cu sediul în municipiul Chișinău, str. Tighina nr. 49/3., of. 54, MD-2001, tel. (00 373) 79 554 429, IDNO 1011600032701,

împuternicește compania **Pharmony SRL**, cu sediul în mun.Chișinău, or.Durlești, str.Durlești, 4, tel: 0 696 46 604, 0 799 844 01, e-mail info@pharmony.md,

1) să depună la Agenția Medicamentului și Dispozitivelor Medicale din Republica Moldova setul de acte în vederea înregistrării de stat al următoarelor dispozitive medicale:

Nr.	Denumire	Model	Tara	Producator
1	Sistem Hidrochirurgie	Versajet II Hydrosurgery Console & Footswitch	Marea Britanie	Smith & Nephew Medical Ltd

2) să îndeplinească toate acțiunile necesare, inclusiv să semneze acte, cereri și alte documente legate de îndeplinirea acestei împuterniciri.

Semnătura reprezentantului _____

Procura este valabilă până pe data de „31" decembrie 2024.

Administrator

L.Ș.

ÎNTREPRINDEREA CU CAPITAL STRĂIN S.R.L. ORTONET IDNO 1011600032701 REPUBLICA MOLDOVA

Semnătura _____

Digitally signed by Șarco Alexandru
Date: 2023.11.24 08:53:16 EET
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 01 din 02.11.2023

Solicitant: ORTONET S.R.L. Moldova, cu sediul în municipiul Chişinău, str. Tighina nr. 49/3., of. 54, MD-2001, tel. (00 373) 79 554 429, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Denumire	Model	Tara	Producator
1	Sistem Hidrochirurgie	Versajet II Hydrosurgery Console & Footswitch	Marea Britanie	Smith & Nephew Medical Ltd

Se anexează următoarele acte:

1. Scrisoarea de autorizare de la producător;
2. Procură de imputernicire.
3. Declarația de conformitate CE;
4. Certificat de conformitate CE;
5. Declarația pe propria răspundere privind veridicitatea datelor.

ÎNTREPRINDEREA CU CAPITAL STRĂIN S.R.L. ORTONET IDNO 1011600032701 REPUBLICA MOLDOVA

Data 02.11.2023 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	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitivelor Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: ORTONET S.R.L. Moldova, cu sediul în municipiul Chişinău, str. Tighina nr. 49/3., of. 54, MD-2001, tel. (00 373) 79 554 429, declar pe proprie răspundere, cunoscând prevederile art. **352**[1], Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea următoarelor dispozitive medicale (producător – Smith & Nephew Medical Ltd):

Nr.	Denumire	Model	Tara	Producator
1	Sistem Hidrochirurgie	Versajet II Hydrosurgery Console & Footswitch	Marea Britanie	Smith & Nephew Medical Ltd

sunt autentice şi corespund realităţii:

Numele, prenumele şi funcţia
Beleus Ilona, Resp. Medical
Semnătura
Data 02.11.2023

ÎNTREPRINDEREA CU CAPITAL STRĂIN S.R.L. ORTONET IDNO 1011600032701 REPUBLICA MOLDOVA

Smith&Nephew
Orthopaedics AG
Oberneuhofstr. 10D
6340 Baar
Switzerland

T +41 41 766 22 22
F +41 41 766 22 90
www.smith-nephew.com

We are smith&nephew

AUTHORIZATION

SMITH&NEPHEW Orthopaedics AG, with offices in Oberneuhofstr. 10D 6340 Baar , Switzerland VAT number CHE 107345392 bank account 01005464001IBAN CH7187801001005464001 BIC DEUTCHZZ at DeutscheBankAG. represented by Bartłomiej Zaręba in quality of Business Unit Manager.

as manufacturer of medical devices (hip and knee prostheses, trauma and endoscopy products, wound management products)

hereby confirm that our exclusive distributor for Romania and Moldavia is the company

MEDICAL ORTOVIT SRL, with offices in 8, Miron Costin str., Bucharest – Romania, registration number J40/5951/1997, VAT no. RO9625593, bank account RO09 RNCB 0075 0352 1435 opened at the Romanian Commercial Bank sector 4 Bucharest, represented by Dr. Mircea Istodorescu in quality of Executive Manager

In order to the safe handling of the medical devices complying with the requirements of the Government Decision no. 418 of 05 June 2014 concerning Medical Devices and the "Guidelines on a Medical Devices Vigilance System" we appoint as our representative in Moldova the company

INTREPRINDEREA CU CAPITAL STRAIN "ORTONET" SRL, with offices in MD-2001, str. Tighina 49/3, of. 54, Mun. Chisinau, Republica Moldova, registration number at the Commerce Registry 2224803315, Unique Registration Code 1011600032701, bank account MFO RNCBMD2X400 at Romanian Commercial Bank BCR – F13, represented by Dr. Vitalie Calaras as General Director

SMITH&NEPHEW
Name: Bartłomiej Zaręba
Position: Business Unit Manager

Smith&Nephew Orthopaedics AG
Smith&Nephew Oberneuhofstrasse 10D
6340 Baar, Switzerland
www.smith-nephew.com

MEDICAL ORTOVIT srl
Mircea Istodorescu
Executive Manager

SC MEDICAL ORTOVIT SRL
J40 / 5951 / 1997
ROMANIA

ORTONET srl
Vitalie Calaras
General Director

Date : 1.03.2015 Baar

Smith & Nephew Medical Ltd. T + 44 (0) 1482 225181
101 Hessle Road F + 44 (0) 1482 328326
Hull, HU3 2BN www.smith-nephew.com

England

EUROPEAN DECLARATION OF CONFORMITY

This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC (as amended).

Manufacturer's Name :	Smith & Nephew Medical Limited
Business Address:	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
Authorised Representative:	Smith & Nephew Orthopaedics GmbH, Alemannenstraβe 14, 78532 Tuttlingen, Germany
Medical Devices:	VERSAJET II Hydrosurgery Console & Footswitch
Classification:	Class IIb Non-Sterile
GMDN Code and Term:	36961: Water jet knife system generator
Scope of Application:	All batches supplied to which the Declaration of Conformity Procedure has been applied.
Declaration:	Conformity of the product has been assessed in accordance with Annex II of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.
Verification Certificate(s):	EC Certificate No. CE 00356 Full Quality Assurance. Notified Body No. 2797 (British Standards Institution) British Standards Institution. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485) British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
Standards Applied:	BS EN ISO 780:2015 BS EN 1041: 2008 BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 14971:2019 BS EN ISO 15223-1:2016 IEC 60601-1:2005 +AMD1:2012 3.1 Edition IEC 60601-1-2:2014 4th Edition IEC 60601-1-6:2010 3rd Edition

Smith & Nephew Medical Ltd.
101 Hessle Road
Hull, HU3 2BN
T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
www.smith-nephew.com
England

	IEC 62366:2007 BS EN 62304:2006+A1:2015 (IEC 62304:2006) BS EN 50581:2012 IEC/ EN 62321:2009 Restriction of Hazardous Substances (RoHS) Directive – 2011/65/EU ISTA 2A: 2011
Product Codes:	

Code	Size
66800039	15in W x 11.8in D x 5.8in H / 38.1cm W x 30cm D x 14.8cm H
66800472	7.5in W x 7.25in D x 2in H / 19cm W x 18.4cm D x 5cm H
66800474	N/A

Authorised Signatory:	
Name:	KEN FERGUSSON
Position:	SENIOR REGULATORY AFFAIRS MANAGER
Signed:	
Dated:	29 JAN 2024
Certificate Reference:	HU/137 issue 08

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00356**

Issued To: **Smith & Nephew Medical Ltd**
101 Hessle Road
Hull
HU3 2BN
United Kingdom

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-05** Date: **2020-01-31** Expiry Date: **2024-05-26**

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Certificate No: CE 00356

Certificate Scope:

The design and manufacture of sterile or non-sterile wound management products in the following categories: wound dressings (see supplementary page), medicated wound dressings, wound dressings utilising animal derived materials (porcine gelatin), medicated bandages, medicated bandages utilising animal derived materials (porcine gelatine), cavity wound dressings, wound preparations, wound monitoring devices, multi-layer bandage systems, Negative Pressure Wound Therapy Systems (NPWT), abdominal dressing kits for use with NPWT, drain kits and drain accessory kits for use with NPWT, and hydrosurgery systems for wound debridement.

Those aspects of Annex II relating to securing and maintaining sterilty in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.

First Issued: **1994-12-05** Date: **2020-01-31** Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00356

Issued To:

Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Number	Device Name	Intended Use per IFU
Class III		
MD 0301 MDS 7001 MDS 7006	Antimicrobial wound dressings	Refer to Design Examination certificates: CE 01105 CE 01409 CE 01714 CE 511078 CE 518880 CE 521887 CE 544419 CE 547893 CE 568730 CE 90692 CE 96076
MD 0301 MDS 7002 MDS 7006	Wound dressings containing porcine gelatine	Refer to Design Examination certificates: CE 01714 CE 650269

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United Kingdom

Number	Device Name	Intended Use per IFU
Class IIb		
MD 0301	Foam wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds. Can also be used for pressure ulcer prevention
MD 0301	Hydrogel wound dressings	Management of shallow and deep open wounds healing by secondary intent
MD 0301	Odour absorbing non-woven wound dressings	For use on malodorous, partial to full thickness wounds and as a secondary dressing for superficial to full thickness wounds
MD 0303	Wound preparation devices	For the improvement/ management of the wound environment to promote healing in acute and chronic wounds
MD 0301	Superabsorbent wound dressings	For the treatment and management of exuding wounds

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Number	Device Name	Intended Use per IFU
MD 0301	Multi-layer bandage systems	For the management and treatment of venous leg ulcers and associated conditions
MD 0301	Alginate wound dressings	To treat pressure sores and venous leg ulcers, with moderate to heavy exudate. To facilitate the control of minor bleeding.
MD 0301	Gauze wound dressings	For the management of partial and full thickness wounds. For post-surgical covering over epithelial autograft sites and a means of stenting or anchoring skin substitutes. Can be used in conjunction with S&N Negative Pressure Wound Therapy (NPWT) systems
MD 1104	Hydrosurgery systems	Intended for wound debridement (acute, chronic wounds and burns), soft tissue debridement and cleansing of the surgical site

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Number	Device Name	Intended Use per IFU
MD 0301	Cellulose based wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds
MD 0301	Hydrocolloid wound dressings	For use in the management of dry or lightly exuding wounds to moderately exuding wounds
MD 1103	Single use negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials
MD 1103	Traditional negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials

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Number	Device Name	Intended Use per IFU
MD 0301	Abdominal dressing kits	Indicated for temporary bridging of abdominal wall openings where primary closure is not possible and / or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome
MD 0303	Wound drainage kits	Intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems

First Issued: **1994-12-05** Date: **2020-01-31** Expiry Date: **2024-05-26**

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Number	Device Name	Intended Use per IFU
Class IIa		
MD 0302	Skin closure devices	--
MD 0301	Film wound dressings	--
MD 0301	Tulle Gras wound dressings	--
MD 0301	Foam wound dressings	--
MD 0301	Hydrogel wound dressings	--

First Issued: **1994-12-05** Date: **2020-01-31** Expiry Date: **2024-05-26**

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