

IDNO: 1007600044280;
adresa: mun. Chişinău, str. Decebal 82-90
tel. 022 808 002, 022 808 003
e-mail: oxivit.medical@gmail.com



Anexa nr. 23
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

Specificații de Preț

Numărul procedurii de achiziție:				ocds-b3wdp1-MD-1643797469914 din 08.02.2022								
Obiectul achiziției:				Proteze valvulare pentru chirurgia cardiacă								
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Cantitatea	Unitatea de măsură	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare	Cod CPV	Clasificație bugetară (IBAN)	Discount %
1	2	3	4	5	6	7	8	9	10	11	12	13
2	Inel rigid pentru anuloplastie. N 30		5	Buc.	9 500.00	9 500.00	47 500.00	47 500.00	la solicitare timp de 5 zile	33100000-1	-	-
3	Inel rigid pentru anuloplastie. N 32		5	Buc.	9 500.00	9 500.00	47 500.00	47 500.00	la solicitare timp de 5 zile	33100000-1	-	-
5	Clei biologic Bioglu, seringă 2 ml		2	buc	7 312.64	8 775.16	14 625.28	17 550.32	la solicitare timp de 5 zile	33100000-1	-	-
6	Clei biologic Bioglu, seringă 5 ml		3	buc	10 154.93	12 185.91	30 464.79	36 557.73	la solicitare timp de 5 zile	33100000-1	-	-
TOTAL Oferta							140 090.07	149 108.05				

Semnat: _____ Numele, Prenumele: Dmitrii Kojevnikov În calitate de: Administrator

Ofertantul: S.C. OXIVIT-MED S.R.L Adresa: mun. Chişinău, str. Decebal 82-90

Specificații Tehnice

Numărul procedurii de achiziție:						ocds-b3wdp1-MD-1643797469914 din 08.02.2022		
Obiectul achiziției:						Proteze valvulare pentru chirurgia cardiacă		
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8	9
2	Inel rigid pentru anuloplastie. N 30		RING 680R30 PROFILE 3D 26L MEXICO	SUA	Medtronic	Mitrale-inel rigid pentru plastia valvei mitrale in trei dimensiuni, pentru inelul anterior sa fie cu forma concavă,-constructia inelului sa conforma cu geometria normala a inelului anular uman-constructie dintrun miez de titan supramodelat cu silicon si acoperit cu pinza poliesterica-sa permita vizualizarea radiografica a dispozitivului-sa prezinte certificat de calitate conform standartelor internationale ISO, CE	Mitrale-inel rigid pentru plastia valvei mitrale in trei dimensiuni, pentru inelul anterior sa fie cu forma concavă,-constructia inelului sa conforma cu geometria normala a inelului anular uman-constructie dintrun miez de titan supramodelat cu silicon si acoperit cu pinza poliesterica-sa permita vizualizarea radiografica a dispozitivului-sa prezinte certificat de calitate conform standartelor internationale ISO, CE	ISO, CE
3	Inel rigid pentru anuloplastie. N 32		RING 680R32 PROFILE 3D 26L MEXICO	SUA	Medtronic	Mitrale-inel rigid pentru plastia valvei mitrale in trei dimensiuni, pentru inelul anterior sa fie cu forma concavă,-constructia inelului sa conforma cu geometria normala a inelului anular uman-constructie dintrun miez de titan supramodelat cu silicon si acoperit cu pinza poliesterica-sa permita vizualizarea radiografica a dispozitivului-sa prezinte certificat de calitate conform standartelor internationale ISO, CE	Mitrale-inel rigid pentru plastia valvei mitrale in trei dimensiuni, pentru inelul anterior sa fie cu forma concavă,-constructia inelului sa conforma cu geometria normala a inelului anular uman-constructie dintrun miez de titan supramodelat cu silicon si acoperit cu pinza poliesterica-sa permita vizualizarea radiografica a dispozitivului-sa prezinte certificat de calitate conform standartelor internationale ISO, CE	ISO, CE
5	Clei biologic Bioglu, seringă 2 ml		BioGlue, of 2mL syringe	SUA	Cryolife	Lipici chirurgical (clei biologic) pentru lipirea peretilor aortei si controlul hemostazei. Siringa preumpluta cu 2 componente Cantitatea 15 gr Conținutul: Gelatină, Resorcină, Formaldehidă Setul format din: - 1 seringă de 2 ml care este compus din ser albumina bovină și glutaraldehidă -4 cateter aplicator Setul să fie steril.	Lipici chirurgical (clei biologic) pentru lipirea peretilor aortei si controlul hemostazei. Siringa preumpluta cu 2 componente Cantitatea 15 gr Conținutul: Gelatină, Resorcină, Formaldehidă Setul format din: - 1 seringă de 2 ml care este compus din ser albumina bovină și glutaraldehidă -4 cateter aplicator Setul să fie steril.	ISO, CE
6	Clei biologic Bioglu, seringă 5 ml		BioGlue, of 5mL syringe	SUA	Cryolife	Lipici chirurgical (clei biologic) pentru lipirea peretilor aortei si controlul hemostazei. Siringa preumpluta cu 2 componente Cantitatea 15 gr Conținutul: Gelatină, Resorcină, Formaldehidă Setul format din: - 1 seringă de 5 ml care este compus din ser albumina bovină și glutaraldehidă -4 cateter aplicator Setul să fie steril.	Lipici chirurgical (clei biologic) pentru lipirea peretilor aortei si controlul hemostazei. Siringa preumpluta cu 2 componente Cantitatea 15 gr Conținutul: Gelatină, Resorcină, Formaldehidă Setul format din: - 1 seringă de 5 ml care este compus din ser albumina bovină și glutaraldehidă -4 cateter aplicator Setul să fie steril.	ISO, CE

Semnat: _____ Numele, Prenumele: Dmitrii Kojevnikov În calitate de: Administrator

Ofertantul: S.C. OXIVIT-MED S.R.L Adresa: mun. Chişinău, str. Decebal 82-90

OXIVIT MED

FORMULAR INFORMATIV DESPRE OFERTANT

S.C. OXIVIT-MED S.R.L
Administrator: Dmitrii Kojevnikov
Adresa poștală: mun. Chișinău, str. Decebal 82-90
Tel./Fax: 022 808 002, 022 808 003
E-mail: info@oxivit-med.com; oxivit.medical@gmail.com
Cod IBAN: MD09MO2224ASV23488147100
Banca: „Mobiasbanca OTP Group” S.A
Codul băncii: MOBBMD22
Cod fiscal: 1007600044280
Cod TVA: 0306300

Cu respect,
Dmitrii Kojevnikov
Administrator

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

ISO 9001:2015
EN ISO 13485:2016

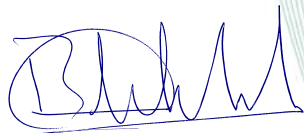
Scope:

Sales, order management, warehousing and distribution of medical devices.
Including regulatory affairs, post market surveillance, technical service, customer education and spine
loaner operations

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

Different scope

Medtronic Trading NL B.V.
Larixplein 4
5616 VB Eindhoven
The Netherlands

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Italia S.p.A.
Via Varesina 162
20156 Milano
Italy

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Danmark A/S.
Arne Jacobsens Alle 17
2300 Copenhagen
Denmark

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Finland Oy
Lentajantie 3
01530 Vantaa
Finland

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic AB
P.O. Box 1034
164 21 Kista
Sweden

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.
Waterfall Distribution Campus CNR
K101 and Bridal Veil Road Waterfall
Midrand
1685 Gauteng
South Africa

Sales, order management, warehousing and distribution of medical devices. Including customer education and spine loaner operations.

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk. Akkom Ofis Park
Laodik Plaza Sitesi B Blok Apt: 2/8
34764 Umraniye - Istanbul
Turkey

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Ibérica S.A.
Calle de Maria de Portugal, 11
28050 Madrid
Spain

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Ibérica S.A.
WTC Almeda Park Placa de la Pau, s/n.
Edificio 7, 3 piso Cornellà de Llobregat
08940 Barcelona
Spain

Sales, order management and distribution of medical devices.

Medtronic Portugal LDA-
Rua Tomas da Fonseca Torre E, 11
 piso
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices
including customer education.

Warehousing and distribution of medical devices, including spine
loaner operations

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices.
Including customer education.

Warehousing and distribution of medical devices, including spine
loaner operations.

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

Medtronic GmbH
Mollsfeld 12
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

Medtronic Österreich GmbH
Millennium Tower, 20th floor Handelskai
94-96
1200 Wien
Austria

Sales, order management, warehousing and distribution of
medical devices. Including customer education

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

Sales, order management, warehousing and distribution of
medical devices. Including customer education

Medtronic France SAS
9, boulevard Romain Rolland
75014 Paris
France

Sales, order management and distribution of medical devices.
Including customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Hellas S.A. Diabetes Shop
Mesogeion Avenue 2-4
115 27 Athens
Greece

Sales, order management and distribution of diabetes medical
devices. Including customer education.

Medtronic Romania SRL
Ploiesti 42-44, Building B, B2 Wing, 2nd
floor, district 1 Baneasa Business &
Technology Park
013696 Bucharest
Romania

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Hungária Kft.
Bocskai ut 134-146 Cepule 3. emelet
1113 Budapest
Hungary

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Serbia Ltd.
Bulevar Zorana Djindjica, 64a
11070 Belgrade
Serbia

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Poland Sp.z o.o Medtronic
Customer Care Center of Experience
Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzliya
Israel

Import, sales, order management and distribution of medical
devices.
Including customer education

Medtronic Czechia s.r.o.
Prosek Point, Budova B, Prosecka
852/66
852 66 Praha
Czech Republic

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Bulgaria EOOD
48 Sitnyakovo blvd., R-N OBORISHT
DISTR., floor 7
1505 Sofia
Bulgaria

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Limited
Building 9, Croxley ParkHatters Ln
WD18 8WW Watford
United Kingdom

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Ireland Limited
Block 3090-3094 Lake Drive, Citywest
Business Campus
D24 NW2F Dublin
Ireland

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic B.V.
Medtronic Service & Repair EMEA
Jan Campertstraat 21-A
6416 SG Heerlen

Order management, warehousing and technical service of
medical devices including field service EMEA.

Medtronic Slovakia s.r.o.
CBC III, Karadzicova 12
821 08 Bratislava
Slovak Republic

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Belgium
Burgemeester E. Demunterlaan 5
1090 Brussel
Belgium

Sales, Order Management and distribution of medical devices.
Including customer education

Medtronic Croatia
Folnegoviceva 1c
10000 Zagreb
Croatia

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Slovenia
Ameriska Ulica 8
1000 Ljubljana
Slovenia

Sales, order management and distribution of medical devices

Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 039709 1279 Rev. 00

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway
Minneapolis MN 55432
USA

**Product Category(ies): Tissue Heart Valves,
Annuloplasty Rings and Bands
and related Accessories for
Surgical Implants, and Temporary Pacing
Lead Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150078

Valid from: 2019-11-15

Valid until: 2024-05-26

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 039709 1279 Rev. 00

Facility(ies):

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja
California, MEXICO

Medtronic Heart Valves Division
1941 Blair Avenue, Santa Ana CA 92705, USA

Medtronic Heart Valves Division
1851 E. Deere Avenue, Santa Ana, CA 92705, USA

Medtronic Fabrication S.A.S. Zone Industrielle SUD
Route D'Anor, 59610 Fourmies, FRANCE

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the Medical Devices Directive 93/42/EEC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:

CryoLife, Inc.

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

PRODUCT NAME:

BioGlue© Surgical Adhesive

PRODUCT DESCRIPTION:

BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue.

DESIGN DOSSIER REFERENCE: document #TF00007.003, revision 003, dated 31 May 2017

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Approval Certificate Number: MDD – 0015237



Chris Koci

Issued By: Lloyd's Register Quality Assurance Ltd



Lloyd's
Register

EC DESIGN EXAMINATION CERTIFICATE CERTIFICATE 0949334 SUPPLEMENT

Certificate Identity Number: 10039484

CryoLife, Inc.

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	21 November 2017	Renewal under jobs 1222716 & 1223002

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Chris Koci

Issued By: Lloyd's Register Quality Assurance Ltd

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07.2007

Bordeianu Tatiana, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0067985





REPUBLICA MOLDOVA
LICENȚĂ

Seria A MMII

Nr. 044647

Denumirea autorității de licențiere

Camera de Licențiere

**Denumirea, forma juridică de organizare, sediul
(adresa juridică) a titularului de licență**

**Societatea Comercială „OXIVIT-
MED” S.R.L.**

mun. Chișinău, bd. Decebal, 82, ap. 90

**Data și numărul certificatului de
înregistrare de stat a titularului de licență**

30.07.2007 MD 0067985

**Numărul de înregistrare
a întreprinderii sau IDNO**

1007600044280

Codul fiscal

**Genul de activitate, integral sau parțial,
pentru a cărui desfășurare se eliberează licența**

*** Importul și comercializarea dispozitivelor
medicale ***

Data eliberării licenței

15 octombrie 2012

**Valabilă până la
Prelungită până la: 15.10.2022**

15 octombrie 2017

**Semnătura conducătorului
autorității de licențiere**

Director al Camerei de Licențiere

Valentin GUZNAC

**Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.**