

Specificații Tehnice

Numărul procedurii de achiziție:		ocds-b3wdp1-MD-1686821291794 din 21.06.2023						
Obiectul achiziției:		Consumabile medicale pentru Terapie Intensivă						
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
9	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	CABLE 5433A PATIENT CABLE-PKG 5433A	SUA	Medtronic	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	ISO, CE
10	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	CABLE 5433V PATIENT CABLE-PKG 5433V	SUA	Medtronic	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	ISO, CE
11	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392	CABLE 5833SL SURGICAL DISP SM CLIP 12FT	SUA	Medtronic	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392 . Lungime mai mare de 3 metri	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392 . Lungime mai mare de 3 metri	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

Specificații de Preț

Numărul procedurii de achiziție: ocds-b3wdp1-MD-1686821291794 din 21.06.2023												
Obiectul achiziției: Consumabile medicale pentru Terapie Intensivă												
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Unitatea de măsură	Cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare	Cod CPV	Clasificatie bugetara (IBAN)	Discount %
1	2	3	4	5	6	7	8	9	10	11	12	13
9	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 A	Bucată	2	5 320.00	6 384.00	10 640.00	12 768.00	la solicitare, timp de 2 zile	33100000-1	-	-
10	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	Cablu pentru pacient, pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5433 V	Bucată	2	5 320.00	6 384.00	10 640.00	12 768.00	la solicitare, timp de 2 zile	33100000-1	-	-
11	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392	Cablu chirurgical pentru conectarea electrozilor de stimulare cardiaca temporara, compatibil cu cardiostimulatorul Medtronic model 5392	Bucată	5	2 415.00	2 898.00	12 075.00	14 490.00	la solicitare, timp de 2 zile	33100000-1	-	-
TOTAL Oferta							33 355.00	40 026.00				

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

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

**Către Grupul de lucru pentru evaluarea
Procedurii de achiziție Nr:
ocds-b3wdp1-MD-1686821291794 din 21.06.2023
din cadrul IMSP Institutul de Cardiologie**

DECLARAȚIE

Prin prezenta, SRL „Oxivit-med”, declara ca:

- Va prezenta mostre in termen de 1 zi, la solicitare

Data completării: 19.06.2023

Cu stimă,

Dmitrii Kojevnikov

Administrator

S.C. OXIVIT-MED S.R.L _____

(semnătura)



NSAI

Quality System Approval Certificate Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 253 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For the Product Family

Heart Therapy Delivery Systems

GMDN Code: 17846

*On the basis of examination under the requirements of Annex II, Section 3 of Directive 90/385/EEC,
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product is hereby authorized.*

Registration Number:	253.100
Original Approval:	12 June 2002
Last Amended on:	03 March 2021
Remains valid until:	26 May 2024

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI.
This certificate must be supported by a valid design examination certificate.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



EC Design Examination Certificate

Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 253 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Medtronic, Inc.

**710 Medtronic Parkway
Minneapolis, MN 55432
USA**

For Product Family

Heart Therapy Delivery Systems

GMDN Code: 17846

CONCLUSION of EXAMINATION:

Complies with the requirements of Directive 90/385/EEC on Active Implantable Medical Devices Annex II (4)

Registration Number:	253.100
Original Approval:	12 June 2002
Last Amended on:	03 March 2021
Remains valid until:	26 May 2024

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

**Approved model numbers are included in the associated attachment
Not valid without a valid Annex II Section 3 certificate**

Note: Changes which could affect conformity with the essential requirements of Directive 90/385/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



NSAI

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

File Ref	Model Reference	Detail
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-S59	SelectSite™ C304-S59 Deflectable Catheter System
253.100.34 253.100.35	C304-HIS	SelectSite™ C304-HIS Deflectable Catheter system
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-L69	SelectSite™ C304-L69 Deflectable Catheter System
253.100.13 253.100.19 253.100.21 253.100.35	C304-XL74	SelectSite™ C304-XL74 Deflectable Catheter System
253.100.13 253.100.19 253.100.35	6227DEF	Attain® 6227DEF Deflectable Catheter Delivery System
253.100.23 253.100.26 253.100.33 253.100.35	C315S4	C315S4 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S5	C315S5 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S10	C315S10 Delivery Catheter



NSAI

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.23 253.100.26 253.100.33 253.100.35	C315J	C315J Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315HIS	C315HIS Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H20	C315H20 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H40	C315H40 Delivery Catheter
253.100.27 253.100.33 253.100.35	6250VIS	Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VIC	Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VI-MB2	Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EH	Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EHXL	Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery



NSAI

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.33 253.100.35	6250VI-MPR	Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MP	Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-AM	Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MB2X	Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-45S	Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-50S	Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-57S	Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MPX	Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-3D	Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery



NSAI

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.35 253.100.36	6248VI-90	Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90S	Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90L	Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130	Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130L	Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90P	Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90SP	Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130P	Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System