

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

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 5 din 13.10.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicită 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:

Product: PTA Balloon Dilatation Catheter

Model: Metacross OTW, Metacross RX

BD-L30020MW	BD-L30120MW	BD-L40060MW	BD-L40200MW	BD-L50100MW
BD-L30040MW	BD-L30150MW	BD-L40080MW	BD-L50020MW	BD-L50120MW
BD-L30060MW	BD-L30200MW	BD-L40100MW	BD-L50040MW	BD-L50150MW
BD-L30080MW	BD-L40020MW	BD-L40120MW	BD-L50060MW	BD-L50200MW
BD-L30100MW	BD-L40040MW	BD-L40150MW	BD-L50080MW	BD-L60020MW
BD-L60040MW	BD-L60150MW	BD-L70080MW	BD-L80020MW	BD-L90040MW
BD-L60060MW	BD-L60200MW	BD-L70100MW	BD-L80040MW	BD-L90060MW
BD-L60080MW	BD-L70020MW	BD-L70120MW	BD-L80060MW	BD-L90080MW
BD-L60100MW	BD-L70040MW	BD-L70150MW	BD-L80080MW	BD-LX0020MW
BD-L60120MW	BD-L70060MW	BD-L70200MW	BD-L90020MW	BD-LX0040MW
BD-LX0060MW	BD-L30040CW	BD-L30150CW	BD-L40080CW	BD-L50020CW
BD-LX0080MW	BD-L30060CW	BD-L30200CW	BD-L40100CW	BD-L50040CW
BD-LX2020MW	BD-L30080CW	BD-L40020CW	BD-L40120CW	BD-L50060CW
BD-LX2040MW	BD-L30100CW	BD-L40040CW	BD-L40150CW	BD-L50080CW
BD-L30020CW	BD-L30120CW	BD-L40060CW	BD-L40200CW	BD-L50100CW
BD-L50120CW	BD-L60060CW	BD-L60200CW	BD-L70100CW	BD-L80040CW
BD-L50150CW	BD-L60080CW	BD-L70020CW	BD-L70120CW	BD-L80060CW
BD-L50200CW	BD-L60100CW	BD-L70040CW	BD-L70150CW	BD-L80080CW
BD-L60020CW	BD-L60120CW	BD-L70060CW	BD-L70200CW	
BD-L60040CW	BD-L60150CW	BD-L70080CW	BD-L80020CW	

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **13.10.2023**

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	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

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:

Product: PTA Balloon Dilatation Catheter

Model: Metacross OTW, Metacross RX

BD-L30020MW	BD-L30120MW	BD-L40060MW	BD-L40200MW	BD-L50100MW
BD-L30040MW	BD-L30150MW	BD-L40080MW	BD-L50020MW	BD-L50120MW
BD-L30060MW	BD-L30200MW	BD-L40100MW	BD-L50040MW	BD-L50150MW
BD-L30080MW	BD-L40020MW	BD-L40120MW	BD-L50060MW	BD-L50200MW
BD-L30100MW	BD-L40040MW	BD-L40150MW	BD-L50080MW	BD-L60020MW
BD-L60040MW	BD-L60150MW	BD-L70080MW	BD-L80020MW	BD-L90040MW
BD-L60060MW	BD-L60200MW	BD-L70100MW	BD-L80040MW	BD-L90060MW
BD-L60080MW	BD-L70020MW	BD-L70120MW	BD-L80060MW	BD-L90080MW
BD-L60100MW	BD-L70040MW	BD-L70150MW	BD-L80080MW	BD-LX0020MW
BD-L60120MW	BD-L70060MW	BD-L70200MW	BD-L90020MW	BD-LX0040MW
BD-LX0060MW	BD-L30040CW	BD-L30150CW	BD-L40080CW	BD-L50020CW
BD-LX0080MW	BD-L30060CW	BD-L30200CW	BD-L40100CW	BD-L50040CW
BD-LX2020MW	BD-L30080CW	BD-L40020CW	BD-L40120CW	BD-L50060CW
BD-LX2040MW	BD-L30100CW	BD-L40040CW	BD-L40150CW	BD-L50080CW
BD-L30020CW	BD-L30120CW	BD-L40060CW	BD-L40200CW	BD-L50100CW
BD-L50120CW	BD-L60060CW	BD-L60200CW	BD-L70100CW	BD-L80040CW
BD-L50150CW	BD-L60080CW	BD-L70020CW	BD-L70120CW	BD-L80060CW
BD-L50200CW	BD-L60100CW	BD-L70040CW	BD-L70150CW	BD-L80080CW
BD-L60020CW	BD-L60120CW	BD-L70060CW	BD-L70200CW	
BD-L60040CW	BD-L60150CW	BD-L70080CW	BD-L80020CW	

Sunt autentice și corespund realității

Alexandru Grabazei, director

Semnătura _____

Data: **13.10.2023**



**Terumo Europe NV
Emerging Market Division**

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 13 08
Fax: +32 16 38 16 01

www.terumo-europe.com

To: Whom It May Concern

Ref: 2023/007/IS/MI

Leuven, January 18, 2023

Letter of Authorization

We, begin company-manufacturer **Terumo Europe N.V. (Belgium)**;
and being the European Authorized representative of company-manufacturer **Terumo Corporation, Terumo Medical Corporation, Terumo Clinical Supply and Terumo Medical Products (Hangzhou)**;
and being the appointed distributor for products from the company-manufacturer **PendraCare, MicroVention Europe, MicroVention Inc and Kaneka Corporation**;

hereby appoint following company (hereinafter - "Company"):

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of following medical products and devices manufactured and/or distributed by us:

Accuforce PTCA dilatation catheter (RX)
Angio-Seal VIP Vascular Closure Device
Azur Detachment Controller
Azur Peripheral Coil System
Climber Guiding Catheter
Croserio RX PTA Balloon Dilatation Catheter
Crosstella OTW PTA Balloon Dilatation Catheter
Destination Guiding Sheath (*Terumo Corporation and Terumo Medical Corporation*)
Eliminate Aspiration catheter
FemoSeal Vascular Closure System
Finecross MG Coronary Micro-Guide catheter
Glidesheath Slender Hydrophilic Coated Introducer Sheath
Heartrail II Guiding Catheter
HydroPearl Compressible Microspheres for Embolisation
LifePearl Drug-elutable microspheres for embolisation
Metacross® OTW PTA Balloon Dilatation Catheter
Metacross® RX PTA Balloon Dilatation Catheter
Navicross Support Catheter
Occlusafe Temporary Occlusion Balloon Catheter
Outlook Angiographic Catheter
Progreat Micro Catheter System (*Terumo Corporation and Terumo Clinical Supply*)
Radifocus Glidecath Angiographic Catheter (*Terumo Corporation and Terumo Europe*)

Radifocus Guide Wire GT with Gold Coil
Radifocus Guide Wire M (*Terumo Corporation and Terumo Europe*)
Radifocus Guide Wire M Non-Vascular
RADIFOCUS® Glidewire Advantage™
RADIFOCUS® Glidewire Advantage™ Track
Radifocus Obturator
Radifocus Torque Device (*Terumo Corporation and Terumo Medical Products (Hangzhou)*)
Radifocus Vessel Dilator
Radifocus OPTITORQUE Angiographic Catheter (*Terumo Corporation and Terumo Europe*)
Radifocus Introducer II (Transradial Kit)
Radifocus Introducer II
Roadsaver Carotid Artery Stent
Runthrough® NS Extension Wire PTCA Guide Wire
Runthrough® NS PTCA Guide Wire
Ryujin Plus PTCA dilatation catheter (RX)
Senri® PTA Balloon Dilatation catheter
Tercross® PTA Dilatation Catheter (OTW)
Ryurei PTCA Dilatation Catheter
TR Band Radial Artery Haemostasis Band
Ultimaster Sirolimus eluting coronary stent system
Ultimaster Tansei Sirolimus eluting coronary stent system
Ultimaster Nagomi Sirolimus eluting coronary stent system

Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose, the company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, after consultation with Regulatory department of Terumo Europe N.V, to conduct any field actions which may be necessary, in accordance with legislation of Republic of Moldova.

Registration certificates must be issued in the name of Terumo Europe N.V.

This authorization letter is valid for a period of 12 /twelve/ months from the date of issue, unless revoked earlier by Terumo Europe N.V.

For and behalf of Terumo Europe N.V.:


Valérie Boydens

Director Regulatory Affairs
Terumo Europe NV

TERUMO
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 LEUVEN, BELG



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 024736 0061 Rev. 01

Manufacturer:

KANEKA Corporation

3-18, 2-Chome, Nakanoshima, Kita-ku

Osaka-city, OSAKA

530-8288 JAPAN

Product Category(ies): Peripheral angioplasty balloon catheter

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.:

JNQ235039027

Valid from:

2020-05-11

Valid until:

2024-05-26

Date,

2020-05-11

Christoph Dicks

Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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ZLG-BS-244.10.08



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EC Certificate

Full Quality Assurance System

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No. G1 024736 0061 Rev. 01

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Report No.:

JNQ235039027

Valid from:

2020-05-11

Valid until:

2024-05-26

Date,

2020-05-11

Christoph Dicks

Head of Certification/Notified Body

DECLARATION OF CONFORMITY

1. Manufacturer: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA
530-8288, JAPAN
2. European representative: **KANEKA MEDICAL EUROPE N.V.**
Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product: **Metacross OTW**
PTA Balloon Dilatation Catheter
4. Catalogue No.: see Attachment
5. Classification: Class IIa,
Rule 6 of annex IX of the MDD 93/42/EEC
6. Conformity assessment route: Annex II excluding Section 4 of the MDD 93/42/EEC applied

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

7. Standard applied: See the List of Applied Standards in Chapter 7A of the Device Documentation of Metacross OTW (No: MEG-TDA1b/08)
8. Notified body: TÜV SÜD Product Service GmbH (Identification No. 0123)
Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate: G1 024736 0061 Rev. 01

10. Start of CE-marking: **LOT No. SR091318**

11. Place, Date of Issue: **Osaka, Japan** **2021-09-17**
Place Date (yyyy-mm-dd)

12. Signature: 
Kazuaki Sanaka (QMS Management Representative)

Attachment

Model: Metacross OTW

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L30020SW	3.0	20	65
BD-L30040SW	3.0	40	65
BD-L30060SW	3.0	60	65
BD-L30080SW	3.0	80	65
BD-L30100SW	3.0	100	65
BD-L30120SW	3.0	120	65
BD-L30150SW	3.0	150	65
BD-L30200SW	3.0	200	65
BD-L40020SW	4.0	20	65
BD-L40040SW	4.0	40	65
BD-L40060SW	4.0	60	65
BD-L40080SW	4.0	80	65
BD-L40100SW	4.0	100	65
BD-L40120SW	4.0	120	65
BD-L40150SW	4.0	150	65
BD-L40200SW	4.0	200	65
BD-L50020SW	5.0	20	65
BD-L50040SW	5.0	40	65
BD-L50060SW	5.0	60	65
BD-L50080SW	5.0	80	65
BD-L50100SW	5.0	100	65
BD-L50120SW	5.0	120	65
BD-L50150SW	5.0	150	65
BD-L50200SW	5.0	200	65
BD-L60020SW	6.0	20	65
BD-L60040SW	6.0	40	65
BD-L60060SW	6.0	60	65
BD-L60080SW	6.0	80	65
BD-L60100SW	6.0	100	65
BD-L60120SW	6.0	120	65
BD-L60150SW	6.0	150	65
BD-L60200SW	6.0	200	65
BD-L70020SW	7.0	20	65
BD-L70040SW	7.0	40	65
BD-L70060SW	7.0	60	65
BD-L70080SW	7.0	80	65
BD-L70100SW	7.0	100	65
BD-L70120SW	7.0	120	65
BD-L70150SW	7.0	150	65
BD-L70200SW	7.0	200	65
BD-L80020SW	8.0	20	65
BD-L80040SW	8.0	40	65
BD-L80060SW	8.0	60	65

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L80080SW	8.0	80	65
BD-L90020SW	9.0	20	65
BD-L90040SW	9.0	40	65
BD-L90060SW	9.0	60	65
BD-L90080SW	9.0	80	65
BD-LX0020SW	10.0	20	65
BD-LX0040SW	10.0	40	65
BD-LX0060SW	10.0	60	65
BD-LX0080SW	10.0	80	65
BD-LX2020SW	12.0	20	65
BD-LX2040SW	12.0	40	65
BD-L30020MW	3.0	20	90
BD-L30040MW	3.0	40	90
BD-L30060MW	3.0	60	90
BD-L30080MW	3.0	80	90
BD-L30100MW	3.0	100	90
BD-L30120MW	3.0	120	90
BD-L30150MW	3.0	150	90
BD-L30200MW	3.0	200	90
BD-L40020MW	4.0	20	90
BD-L40040MW	4.0	40	90
BD-L40060MW	4.0	60	90
BD-L40080MW	4.0	80	90
BD-L40100MW	4.0	100	90
BD-L40120MW	4.0	120	90
BD-L40150MW	4.0	150	90
BD-L40200MW	4.0	200	90
BD-L50020MW	5.0	20	90
BD-L50040MW	5.0	40	90
BD-L50060MW	5.0	60	90
BD-L50080MW	5.0	80	90
BD-L50100MW	5.0	100	90
BD-L50120MW	5.0	120	90
BD-L50150MW	5.0	150	90
BD-L50200MW	5.0	200	90
BD-L60020MW	6.0	20	90
BD-L60040MW	6.0	40	90
BD-L60060MW	6.0	60	90
BD-L60080MW	6.0	80	90
BD-L60100MW	6.0	100	90
BD-L60120MW	6.0	120	90
BD-L60150MW	6.0	150	90
BD-L60200MW	6.0	200	90
BD-L70020MW	7.0	20	90
BD-L70040MW	7.0	40	90
BD-L70060MW	7.0	60	90
BD-L70080MW	7.0	80	90
BD-L70100MW	7.0	100	90

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L70120MW	7.0	120	90
BD-L70150MW	7.0	150	90
BD-L70200MW	7.0	200	90
BD-L80020MW	8.0	20	90
BD-L80040MW	8.0	40	90
BD-L80060MW	8.0	60	90
BD-L80080MW	8.0	80	90
BD-L90020MW	9.0	20	90
BD-L90040MW	9.0	40	90
BD-L90060MW	9.0	60	90
BD-L90080MW	9.0	80	90
BD-LX0020MW	10.0	20	90
BD-LX0040MW	10.0	40	90
BD-LX0060MW	10.0	60	90
BD-LX0080MW	10.0	80	90
BD-LX2020MW	12.0	20	90
BD-LX2040MW	12.0	40	90
BD-L30020CW	3.0	20	135
BD-L30040CW	3.0	40	135
BD-L30060CW	3.0	60	135
BD-L30080CW	3.0	80	135
BD-L30100CW	3.0	100	135
BD-L30120CW	3.0	120	135
BD-L30150CW	3.0	150	135
BD-L30200CW	3.0	200	135
BD-L40020CW	4.0	20	135
BD-L40040CW	4.0	40	135
BD-L40060CW	4.0	60	135
BD-L40080CW	4.0	80	135
BD-L40100CW	4.0	100	135
BD-L40120CW	4.0	120	135
BD-L40150CW	4.0	150	135
BD-L40200CW	4.0	200	135
BD-L50020CW	5.0	20	135
BD-L50040CW	5.0	40	135
BD-L50060CW	5.0	60	135
BD-L50080CW	5.0	80	135
BD-L50100CW	5.0	100	135
BD-L50120CW	5.0	120	135
BD-L50150CW	5.0	150	135
BD-L50200CW	5.0	200	135
BD-L60020CW	6.0	20	135
BD-L60040CW	6.0	40	135
BD-L60060CW	6.0	60	135
BD-L60080CW	6.0	80	135
BD-L60100CW	6.0	100	135
BD-L60120CW	6.0	120	135
BD-L60150CW	6.0	150	135

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L60200CW	6.0	200	135
BD-L70020CW	7.0	20	135
BD-L70040CW	7.0	40	135
BD-L70060CW	7.0	60	135
BD-L70080CW	7.0	80	135
BD-L70100CW	7.0	100	135
BD-L70120CW	7.0	120	135
BD-L70150CW	7.0	150	135
BD-L70200CW	7.0	200	135
BD-L80020CW	8.0	20	135
BD-L80040CW	8.0	40	135
BD-L80060CW	8.0	60	135
BD-L80080CW	8.0	80	135
BD-L90020CW	9.0	20	135
BD-L90040CW	9.0	40	135
BD-L90060CW	9.0	60	135
BD-L90080CW	9.0	80	135
BD-LX0020CW	10.0	20	135
BD-LX0040CW	10.0	40	135
BD-LX0060CW	10.0	60	135
BD-LX0080CW	10.0	80	135
BD-LX2020CW	12.0	20	135
BD-LX2040CW	12.0	40	135

DECLARATION OF CONFORMITY

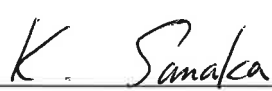
1. Manufacturer: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city,
OSAKA 530-8288, JAPAN
2. European representative: **KANEKA MEDICAL EUROPE N.V.**
Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product: **Metacross RX**
PTA Balloon Dilatation Catheter
4. Catalogue No.: see Attachment
5. Classification: Class IIa, Rule 6 of annex IX of the MDD 93/42/EEC
6. Conformity assessment route: Annex II excluding Section 4 of the MDD 93/42/EEC applied

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATIONS OF CONFORMITY. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

7. Standard applied: See the List of Applied Standards in Chapter 7A of the Device Documentation of Metacross RX (No: MEG-TDA1a/11)
8. Notified body: TÜV SÜD Product Service GmbH (Identification No. 0123)
Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate: G1 024736 0061 Rev.01

10. Start of CE-marking: **LOT No. SR091088**

11. Place, Date of Issue: **Osaka, Japan** **2021-09-15**
Place Date (yyyy-mm-dd)

12. Signature: 
Kazuaki Sanaka (QMS Management Representative)

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L30020MR	3.0	20	900
Metacross RX	BD-L30040MR	3.0	40	900
Metacross RX	BD-L30060MR	3.0	60	900
Metacross RX	BD-L30080MR	3.0	80	900
Metacross RX	BD-L30100MR	3.0	100	900
Metacross RX	BD-L30120MR	3.0	120	900
Metacross RX	BD-L30150MR	3.0	150	900
Metacross RX	BD-L30200MR	3.0	200	900
Metacross RX	BD-L40020MR	4.0	20	900
Metacross RX	BD-L40040MR	4.0	40	900
Metacross RX	BD-L40060MR	4.0	60	900
Metacross RX	BD-L40080MR	4.0	80	900
Metacross RX	BD-L40100MR	4.0	100	900
Metacross RX	BD-L40120MR	4.0	120	900
Metacross RX	BD-L40150MR	4.0	150	900
Metacross RX	BD-L40200MR	4.0	200	900
Metacross RX	BD-L50020MR	5.0	20	900
Metacross RX	BD-L50040MR	5.0	40	900
Metacross RX	BD-L50060MR	5.0	60	900
Metacross RX	BD-L50080MR	5.0	80	900
Metacross RX	BD-L50100MR	5.0	100	900
Metacross RX	BD-L50120MR	5.0	120	900
Metacross RX	BD-L50150MR	5.0	150	900
Metacross RX	BD-L50200MR	5.0	200	900
Metacross RX	BD-L60020MR	6.0	20	900
Metacross RX	BD-L60040MR	6.0	40	900
Metacross RX	BD-L60060MR	6.0	60	900
Metacross RX	BD-L60080MR	6.0	80	900
Metacross RX	BD-L60100MR	6.0	100	900
Metacross RX	BD-L60120MR	6.0	120	900
Metacross RX	BD-L60150MR	6.0	150	900
Metacross RX	BD-L60200MR	6.0	200	900
Metacross RX	BD-L70020MR	7.0	20	900
Metacross RX	BD-L70040MR	7.0	40	900
Metacross RX	BD-L70060MR	7.0	60	900
Metacross RX	BD-L70080MR	7.0	80	900
Metacross RX	BD-L70100MR	7.0	100	900
Metacross RX	BD-L70120MR	7.0	120	900
Metacross RX	BD-L70150MR	7.0	150	900
Metacross RX	BD-L70200MR	7.0	200	900
Metacross RX	BD-L80020MR	8.0	20	900
Metacross RX	BD-L80040MR	8.0	40	900
Metacross RX	BD-L80060MR	8.0	60	900
Metacross RX	BD-L80080MR	8.0	80	900
Metacross RX	BD-L90020MR	9.0	20	900
Metacross RX	BD-L90040MR	9.0	40	900
Metacross RX	BD-L90060MR	9.0	60	900
Metacross RX	BD-L90080MR	9.0	80	900
Metacross RX	BD-LX0020MR	10.0	20	900

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-LX0040MR	10.0	40	900
Metacross RX	BD-LX0060MR	10.0	60	900
Metacross RX	BD-LX0080MR	10.0	80	900
Metacross RX	BD-LX2020MR	12.0	20	900
Metacross RX	BD-LX2040MR	12.0	40	900
Metacross RX	BD-L30020CR	3.0	20	1350
Metacross RX	BD-L30040CR	3.0	40	1350
Metacross RX	BD-L30060CR	3.0	60	1350
Metacross RX	BD-L30080CR	3.0	80	1350
Metacross RX	BD-L30100CR	3.0	100	1350
Metacross RX	BD-L30120CR	3.0	120	1350
Metacross RX	BD-L30150CR	3.0	150	1350
Metacross RX	BD-L30200CR	3.0	200	1350
Metacross RX	BD-L40020CR	4.0	20	1350
Metacross RX	BD-L40040CR	4.0	40	1350
Metacross RX	BD-L40060CR	4.0	60	1350
Metacross RX	BD-L40080CR	4.0	80	1350
Metacross RX	BD-L40100CR	4.0	100	1350
Metacross RX	BD-L40120CR	4.0	120	1350
Metacross RX	BD-L40150CR	4.0	150	1350
Metacross RX	BD-L40200CR	4.0	200	1350
Metacross RX	BD-L50020CR	5.0	20	1350
Metacross RX	BD-L50040CR	5.0	40	1350
Metacross RX	BD-L50060CR	5.0	60	1350
Metacross RX	BD-L50080CR	5.0	80	1350
Metacross RX	BD-L50100CR	5.0	100	1350
Metacross RX	BD-L50120CR	5.0	120	1350
Metacross RX	BD-L50150CR	5.0	150	1350
Metacross RX	BD-L50200CR	5.0	200	1350
Metacross RX	BD-L60020CR	6.0	20	1350
Metacross RX	BD-L60040CR	6.0	40	1350
Metacross RX	BD-L60060CR	6.0	60	1350
Metacross RX	BD-L60080CR	6.0	80	1350
Metacross RX	BD-L60100CR	6.0	100	1350
Metacross RX	BD-L60120CR	6.0	120	1350
Metacross RX	BD-L60150CR	6.0	150	1350
Metacross RX	BD-L60200CR	6.0	200	1350
Metacross RX	BD-L70020CR	7.0	20	1350
Metacross RX	BD-L70040CR	7.0	40	1350
Metacross RX	BD-L70060CR	7.0	60	1350
Metacross RX	BD-L70080CR	7.0	80	1350
Metacross RX	BD-L70100CR	7.0	100	1350
Metacross RX	BD-L70120CR	7.0	120	1350
Metacross RX	BD-L70150CR	7.0	150	1350
Metacross RX	BD-L70200CR	7.0	200	1350
Metacross RX	BD-L80020CR	8.0	20	1350
Metacross RX	BD-L80040CR	8.0	40	1350
Metacross RX	BD-L80060CR	8.0	60	1350
Metacross RX	BD-L80080CR	8.0	80	1350

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L90020CR	9.0	20	1350
Metacross RX	BD-L90040CR	9.0	40	1350
Metacross RX	BD-L90060CR	9.0	60	1350
Metacross RX	BD-L90080CR	9.0	80	1350
Metacross RX	BD-LX0020CR	10.0	20	1350
Metacross RX	BD-LX0040CR	10.0	40	1350
Metacross RX	BD-LX0060CR	10.0	60	1350
Metacross RX	BD-LX0080CR	10.0	80	1350
Metacross RX	BD-LX2020CR	12.0	20	1350
Metacross RX	BD-LX2040CR	12.0	40	1350
Metacross RX	BD-L30020ER	3.0	20	2000
Metacross RX	BD-L30040ER	3.0	40	2000
Metacross RX	BD-L30060ER	3.0	60	2000
Metacross RX	BD-L30080ER	3.0	80	2000
Metacross RX	BD-L30100ER	3.0	100	2000
Metacross RX	BD-L30120ER	3.0	120	2000
Metacross RX	BD-L30150ER	3.0	150	2000
Metacross RX	BD-L30200ER	3.0	200	2000
Metacross RX	BD-L40020ER	4.0	20	2000
Metacross RX	BD-L40040ER	4.0	40	2000
Metacross RX	BD-L40060ER	4.0	60	2000
Metacross RX	BD-L40080ER	4.0	80	2000
Metacross RX	BD-L40100ER	4.0	100	2000
Metacross RX	BD-L40120ER	4.0	120	2000
Metacross RX	BD-L40150ER	4.0	150	2000
Metacross RX	BD-L40200ER	4.0	200	2000
Metacross RX	BD-L50020ER	5.0	20	2000
Metacross RX	BD-L50040ER	5.0	40	2000
Metacross RX	BD-L50060ER	5.0	60	2000
Metacross RX	BD-L50080ER	5.0	80	2000
Metacross RX	BD-L50100ER	5.0	100	2000
Metacross RX	BD-L50120ER	5.0	120	2000
Metacross RX	BD-L50150ER	5.0	150	2000
Metacross RX	BD-L50200ER	5.0	200	2000
Metacross RX	BD-L60020ER	6.0	20	2000
Metacross RX	BD-L60040ER	6.0	40	2000
Metacross RX	BD-L60060ER	6.0	60	2000
Metacross RX	BD-L60080ER	6.0	80	2000
Metacross RX	BD-L60100ER	6.0	100	2000
Metacross RX	BD-L60120ER	6.0	120	2000
Metacross RX	BD-L60150ER	6.0	150	2000
Metacross RX	BD-L60200ER	6.0	200	2000
Metacross RX	BD-L70020ER	7.0	20	2000
Metacross RX	BD-L70040ER	7.0	40	2000
Metacross RX	BD-L70060ER	7.0	60	2000
Metacross RX	BD-L70080ER	7.0	80	2000
Metacross RX	BD-L70100ER	7.0	100	2000
Metacross RX	BD-L70120ER	7.0	120	2000
Metacross RX	BD-L70150ER	7.0	150	2000

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L70200ER	7.0	200	2000
Metacross RX	BD-L80020ER	8.0	20	2000
Metacross RX	BD-L80040ER	8.0	40	2000
Metacross RX	BD-L80060ER	8.0	60	2000
Metacross RX	BD-L80080ER	8.0	80	2000
Metacross RX	BD-L90020ER	9.0	20	2000
Metacross RX	BD-L90040ER	9.0	40	2000
Metacross RX	BD-L90060ER	9.0	60	2000
Metacross RX	BD-L90080ER	9.0	80	2000
Metacross RX	BD-LX0020ER	10.0	20	2000
Metacross RX	BD-LX0040ER	10.0	40	2000
Metacross RX	BD-LX0060ER	10.0	60	2000
Metacross RX	BD-LX0080ER	10.0	80	2000
Metacross RX	BD-LX2020ER	12.0	20	2000
Metacross RX	BD-LX2040ER	12.0	40	2000
R2P Metacross RX	BD-P30020ER	3.0	20	2000
R2P Metacross RX	BD-P30040ER	3.0	40	2000
R2P Metacross RX	BD-P30060ER	3.0	60	2000
R2P Metacross RX	BD-P30080ER	3.0	80	2000
R2P Metacross RX	BD-P30100ER	3.0	100	2000
R2P Metacross RX	BD-P30120ER	3.0	120	2000
R2P Metacross RX	BD-P30150ER	3.0	150	2000
R2P Metacross RX	BD-P30200ER	3.0	200	2000
R2P Metacross RX	BD-P40020ER	4.0	20	2000
R2P Metacross RX	BD-P40040ER	4.0	40	2000
R2P Metacross RX	BD-P40060ER	4.0	60	2000
R2P Metacross RX	BD- P40080ER	4.0	80	2000
R2P Metacross RX	BD- P40100ER	4.0	100	2000
R2P Metacross RX	BD-P40120ER	4.0	120	2000
R2P Metacross RX	BD-P40150ER	4.0	150	2000
R2P Metacross RX	BD-P40200ER	4.0	200	2000
R2P Metacross RX	BD-P50020ER	5.0	20	2000
R2P Metacross RX	BD-P50040ER	5.0	40	2000
R2P Metacross RX	BD-P50060ER	5.0	60	2000
R2P Metacross RX	BD-P50080ER	5.0	80	2000
R2P Metacross RX	BD-P50100ER	5.0	100	2000
R2P Metacross RX	BD-P50120ER	5.0	120	2000
R2P Metacross RX	BD-P50150ER	5.0	150	2000
R2P Metacross RX	BD-P50200ER	5.0	200	2000
R2P Metacross RX	BD-P60020ER	6.0	20	2000
R2P Metacross RX	BD-P60040ER	6.0	40	2000
R2P Metacross RX	BD-P60060ER	6.0	60	2000
R2P Metacross RX	BD-P60080ER	6.0	80	2000
R2P Metacross RX	BD-P60100ER	6.0	100	2000
R2P Metacross RX	BD-P60120ER	6.0	120	2000
R2P Metacross RX	BD-P60150ER	6.0	150	2000
R2P Metacross RX	BD-P60200ER	6.0	200	2000
R2P Metacross RX	BD-P70020ER	7.0	20	2000
R2P Metacross RX	BD-P70040ER	7.0	40	2000

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
R2P Metacross RX	BD-P70060ER	7.0	60	2000
R2P Metacross RX	BD-P70080ER	7.0	80	2000
R2P Metacross RX	BD-P70100ER	7.0	100	2000
R2P Metacross RX	BD-P70120ER	7.0	120	2000
R2P Metacross RX	BD-P70150ER	7.0	150	2000
R2P Metacross RX	BD-P70200ER	7.0	200	2000
R2P Metacross RX	BD-P80020ER	8.0	20	2000
R2P Metacross RX	BD-P80040ER	8.0	40	2000
R2P Metacross RX	BD-P80060ER	8.0	60	2000
R2P Metacross RX	BD-P80080ER	8.0	80	2000