

DECLARATION OF CONFORMITY

1. Manufacturer: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA
530-8288, JAPAN
2. European representative: **KANEKA PHARMA 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/05)
8. Notified body: TÜV SÜD Product Service GmbH (Identification No. 0123)
Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate: G1 17 04 24736 061

10. Start of CE-marking: **LOT No. SP068161**

11. Place, Date of Issue: Osaka, Japan 2018-06-04
Place Date (yyyy-mm-dd)

12. Signature: K. Sanaka
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

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L80060SW	8.0	60	65
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

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
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
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

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
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
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