

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 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/07)
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. SP068159**

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

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

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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

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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

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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