

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: **Senri**
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: EN ISO 13485:2016, EN ISO 14971:2012, EN ISO
11135:2014, EN ISO 10555-1:2013
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. **SR010069**

11. Place, Date of Issue: Osaka, Japan 2019-12-24
Place Date (yyyy-mm-dd)

12. Signature: K. Sanaka
Kazuaki Sanaka (QMS Management representative)

Attachment

Catalogue No.	Balloon Diameter (mm) <La>	Balloon Length (mm) <Lb>	Effective length (cm) <Lc>
BD-S2040M	2.00	40	90
BD-S2060M	2.00	60	90
BD-S2080M	2.00	80	90
BD-S20100M	2.00	100	90
BD-S20120M	2.00	120	90
BD-S20150M	2.00	150	90
BD-S3040M	3.00	40	90
BD-S3060M	3.00	60	90
BD-S3080M	3.00	80	90
BD-S30100M	3.00	100	90
BD-S30120M	3.00	120	90
BD-S30150M	3.00	150	90
BD-S4040M	4.00	40	90
BD-S4060M	4.00	60	90
BD-S4080M	4.00	80	90
BD-S40100M	4.00	100	90
BD-S40120M	4.00	120	90
BD-S40150M	4.00	150	90
BD-S5040M	5.00	40	90
BD-S5060M	5.00	60	90
BD-S5080M	5.00	80	90
BD-S50100M	5.00	100	90
BD-S50120M	5.00	120	90
BD-S50150M	5.00	150	90
BD-S6040M	6.00	40	90
BD-S6060M	6.00	60	90
BD-S6080M	6.00	80	90
BD-S7040M	7.00	40	90
BD-S7060M	7.00	60	90
BD-S7080M	7.00	80	90
BD-S8040M	8.00	40	90
BD-S8060M	8.00	60	90
BD-S6060MH	6.00	60	90
BD-S6080MH	6.00	80	90
BD-S60100MH	6.00	100	90
BD-S60120MH	6.00	120	90
BD-S60150MH	6.00	150	90
BD-S7040MH	7.00	40	90
BD-S7060MH	7.00	60	90
BD-S7080MH	7.00	80	90
BD-S8040MH	8.00	40	90
BD-S8060MH	8.00	60	90
BD-S2040L	2.00	40	150
BD-S2060L	2.00	60	150

Attachment

Catalogue No.	Balloon Diameter (mm) <La>	Balloon Length (mm) <Lb>	Effective length (cm) <Lc>
BD-S2080L	2.00	80	150
BD-S20100L	2.00	100	150
BD-S20120L	2.00	120	150
BD-S20150L	2.00	150	150
BD-S3040L	3.00	40	150
BD-S3060L	3.00	60	150
BD-S3080L	3.00	80	150
BD-S30100L	3.00	100	150
BD-S30120L	3.00	120	150
BD-S30150L	3.00	150	150
BD-S4040L	4.00	40	150
BD-S4060L	4.00	60	150
BD-S4080L	4.00	80	150
BD-S40100L	4.00	100	150
BD-S40120L	4.00	120	150
BD-S40150L	4.00	150	150
BD-S5040L	5.00	40	150
BD-S5060L	5.00	60	150
BD-S5080L	5.00	80	150
BD-S50100L	5.00	100	150
BD-S50120L	5.00	120	150
BD-S50150L	5.00	150	150
BD-S6040L	6.00	40	150
BD-S6060L	6.00	60	150
BD-S6080L	6.00	80	150
BD-S7040L	7.00	40	150
BD-S7060L	7.00	60	150
BD-S7080L	7.00	80	150
BD-S8040L	8.00	40	150
BD-S8060L	8.00	60	150
BD-S6060LH	6.00	60	150
BD-S6080LH	6.00	80	150
BD-S60100LH	6.00	100	150
BD-S60120LH	6.00	120	150
BD-S60150LH	6.00	150	150
BD-S7040LH	7.00	40	150
BD-S7060LH	7.00	60	150
BD-S7080LH	7.00	80	150
BD-S8040LH	8.00	40	150
BD-S8060LH	8.00	60	150