By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 610606**

Issued To: **Shenzhen Shineyard**
Medical Device Company Limited
3/F, Changfeng Industrial Block
No. 3 Liuxian Road, Xin'an
Bao'an District
Shenzhen
Guangdong
518000
China

In respect of:

PBMV Balloon Catheters Sets including Balloon Catheter, Guide Wire, Dilator, Stretching Tube, Stylet, Syringe and Ruler

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2014-01-30** Date: **2018-05-10** Expiry Date: **2019-01-30**

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EC Design-Examination Certificate

Supplementary Information to CE 610606

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Medical Device Company Limited
3/F, Changfeng Industrial Block
No. 3 Liuxian Road, Xin'an
Bao'an District
Shenzhen
Guangdong
518000
China

Product: PBMV Balloon Catheter Sets

Including Balloon Catheter, Guide Wire, Dilator, Stretching Tube, Stylet, Syringe and Ruler

Model Code	Description
PBMV-20S	PBMV Balloon Catheter Set
PBMV-22S	PBMV Balloon Catheter Set
PBMV-24S	PBMV Balloon Catheter Set
PBMV-26S	PBMV Balloon Catheter Set
PBMV-28S	PBMV Balloon Catheter Set
PBMV-30S	PBMV Balloon Catheter Set
PBMV-20YS	PBMV Balloon Catheter Set
PBMV-22YS	PBMV Balloon Catheter Set
PBMV-24YS	PBMV Balloon Catheter Set
PBMV-26YS	PBMV Balloon Catheter Set
PBMV-28YS	PBMV Balloon Catheter Set
PBMV-30YS	PBMV Balloon Catheter Set

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Certificate History

Date	Reference Number	Action
30 January 2014	10145350	First Issue – Transfer from another Notified Body.
05 September 2017	8596045	Change of address of legal manufacturer, move of manufacture and sterilization site, from “Shenzhen Baishizhou” to “Shenzhen Bao’an”.
Current	8907729	Remove “Blue Arrow™” from the device brand name.

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