

EC Design-Examination Certificate

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

No. **CE 597196**
Issued To: **Blue Medical Devices B.V.**
Panovenweg 7
5708 HR Helmond
The Netherlands

In respect of:

Protégé paclitaxel-eluting balloon, PIONEER Paclitaxel-eluting balloon with stent, Protégé NC paclitaxel drug-eluting noncompliant balloon, Welling Medical Protégé, Welling Medical Protégé NC, Welling Medical PIONEER catheters and stents with associated delivery system with paclitaxel-eluting balloon technology for coronary use.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 July 2016**

Date: **14 March 2017**

Expiry Date: **14 March 2022**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 597196

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Protégé, paclitaxel-eluting balloon:

		Diameter (in mm)				
		2.00	2.50	3.00	3.50	4.00
Length (in mm)	10	PRO2010	PRO2510	PRO3010	PRO3510	PRO4010
	15	PRO2015	PRO2515	PRO3015	PRO3515	PRO4015
	20	PRO2020	PRO2520	PRO3020	PRO3520	PRO4020
	30	PRO2030	PRO2530	PRO3030	PRO3530	PRO4030

PIONEER, paclitaxel-eluting balloon with stent

		Diameter (in mm)					
		2.50	2.75	3.00	3.25	3.50	4.00
Length (in mm)	10	PIO2510	PIO2710	PIO3010	PIO3210	PIO3510	PIO4010
	14	PIO2514	PIO2714	PIO3014	PIO3214	PIO3514	PIO4014
	18	PIO2518	PIO2718	PIO3018	PIO3218	PIO3518	PIO4018
	22	PIO2522	PIO2722	PIO3022	PIO3222	PIO3522	PIO4022
	28	PIO2528	PIO2728	PIO3028	PIO3228	PIO3528	PIO4028

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Protégé NC: paclitaxel drug-eluting non compliant balloon

		Diameter (in mm)						
		2.50	2.75	3.00	3.25	3.50	4.00	4.50
Length (in mm)	10	PNC2510	PNC2710	PNC3010	PNC3210	PNC3510	PNC4010	PNC4510
	15	PNC2515	PNC2715	PNC3015	PNC3215	PNC3515	PNC4015	PNC4515
	20	PNC2520	PNC2720	PNC3020	PNC 3220	PNC3520	PNC4020	PNC4520

Welling Medical Protégé

		Diameter (in mm)				
		2.00	2.50	3.00	3.50	4.00
Length (in mm)	10	WPRO2010	WPRO2510	WPRO3010	WPRO3510	WPRO4010
	15	WPRO2015	WPRO2515	WPRO3015	WPRO3515	WPRO4015
	20	WPRO2020	WPRO2520	WPRO3020	WPRO3520	WPRO4020
	30	WPRO2030	WPRO2530	WPRO3030	WPRO3530	WPRO4030

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Welling Medical PIONEER

		Diameter (in mm)					
		2.50	2.75	3.00	3.25	3.50	4.00
Length (in mm)	10	WPIO2510	WPIO2710	WPIO3010	WPIO3210	WPIO3510	WPIO4010
	14	WPIO2514	WPIO2714	WPIO3014	WPIO3214	WPIO3514	WPIO4014
	18	WPIO2518	WPIO2718	WPIO3018	WPIO3218	WPIO3518	WPIO4018
	22	WPIO2522	WPIO2722	WPIO3022	WPIO3022	WPIO3522	WPIO4022
	28	WPIO2528	WPIO2728	WPIO3028	WPIO3228	WPIO3528	WPIO4028

Welling Medical Protégé NC

		Diameter (in mm)						
		2.50	2.75	3.00	3.25	3.50	4.00	4.50
Length (in mm)	10	WPNC2510	WPNC2710	WPNC3010	WPNC3210	WPNC3510	WPNC4010	WPNC4510
	15	WPNC2515	WPNC2715	WPNC3015	WPNC3215	WPNC3515	WPNC4015	WPNC4515
	20	WPNC2520	WPNC2720	WPNC3020	WPNC 3220	WPNC3520	WPNC4020	WPNC4520

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Certificate History

Date	Reference Number	Action
27 July 2016	10160306	First Issue – Transfer from another Notified Body.
14 March 2017	10168854	Certificate renewal.

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