

# EC Design-Examination Certificate

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

**No.** **CE 597193**  
**Issued To:** **Blue Medical Devices B.V.**  
**Panovenweg 7**  
**5708 HR Helmond**  
**The Netherlands**

In respect of:

**Track, XTRM-Track and Welling Medical Track stents with associated delivery system.**

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: **07 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 597193

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### Track, XTRM-Track:

		Diameter (in mm)					
		2.50	2.75	3.00	3.25	3.50	4.00
Length (in mm)	10	XT2510M	XT2710M	XT3010M	XT3210M	XT3510M	XT4010M
	14	XT2514M	XT2714M	XT3014M	XT3214M	XT3514M	XT4014M
	18	XT2518M	XT2718M	XT3018M	XT3218M	XT3518M	XT4018M
	22	XT2522M	XT2722M	XT3022M	XT3222M	XT3522M	XT4022M
	28	XT2528M	XT2728M	XT3028M	XT3228M	XT3528M	XT4028M
	32	XT2532M	XT2732M	XT3032M	XT3232M	XT3532M	XT4032M
		Diameter (in mm)					
Length (in mm)		2.00		2.25		2.50	
	10SV	XT2010S		XT2210S		XT2510S	
	14SV	XT2014S		XT2214S		XT2514S	
	18SV	XT2018S		XT2218S		XT2518S	

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### Welling Medical Track:

		Diameter (in mm)					
		2.50	2.75	3.00	3.25	3.50	4.00
Length (in mm)	10	WTRK2510M	WTRK2710M	WTRK3010M	WTRK3210M	WTRK3510M	WTRK4010M
	14	WTRK2514M	WTRK2714M	WTRK3014M	WTRK3214M	WTRK3514M	WTRK4014M
	18	WTRK2518M	WTRK2718M	WTRK3018M	WTRK3218M	WTRK3518M	WTRK4018M
	22	WTRK2522M	WTRK2722M	WTRK3022M	WTRK3222M	WTRK3522M	WTRK4022M
	28	WTRK2528M	WTRK2728M	WTRK3028M	WTRK3228M	WTRK3528M	WTRK4028M
	32	WTRK2532M	WTRK2732M	WTRK3032M	WTRK3232M	WTRK3532M	WTRK4032M
		Diameter (in mm)					
		2.00	2.25		2.50		
Length (in mm)	10SV	WTRK2010S	WTRK2210S		WTRK2510S		
	14SV	WTRK2014S	WTRK2214S		WTRK2514S		
	18SV	WTRK2018S	WTRK2218S		WTRK2518S		

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## Certificate History

Date	Reference Number	Action
27 July 2016	10160305	First Issue – Transfer from another Notified Body
16 September 2016	10166419	Corrected address error.
07 March 2017	10168856	Certificate renewal

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