

EC Design-Examination Certificate

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

No.**CE 663704**

Issued To:

**BrosMed Medical Co., Ltd
15th Building, SMEs Venture Park
SongShan Lake Hi-Tech Industrial
Development Zone
Dongguan
Guangdong
523808
China**

In respect of:

Apollo (Other brand names: Aperi NC, Origin NC) Balloon Dilatation Catheters

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-09-13**Date: **2021-05-19**Expiry Date: **2023-10-20**

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Device name: Apollo (Other brand names: Aperi NC, Origin NC) Balloon Dilatation Catheters
Intended purpose per IFU: The Apollo (Other brand names: Aperi NC, Origin NC) balloon dilatation catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Balloon dilatation of a stent after implantation.
Classification: Class III

Catalog Number (Apollo)	Catalog Number (Aperi NC)	Catalog Number (Origin NC)	Model, Type
802-2006	442006	ON2006	Ø2.0 x 6mm
802-2008	442008	ON2008	Ø2.0 x 8mm
802-2010	442010	ON2010	Ø2.0 x 10mm
802-2012	442012	ON2012	Ø2.0 x 12mm
802-2015	442015	ON2015	Ø2.0 x 15mm
802-2018	442018	ON2018	Ø2.0 x 18mm
802-2020	442020	ON2020	Ø2.0 x 20mm
802-2022	442022	ON2022	Ø2.0 x 22mm
802-2025	442025	ON2025	Ø2.0 x 25mm
802-2030	442030	ON2030	Ø2.0 x 30mm
802-2206	442206	ON2206	Ø2.25 x 6mm
802-2208	442208	ON2208	Ø2.25 x 8mm

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Catalog Number (Apollo)	Catalog Number (Aperi NC)	Catalog Number (Origin NC)	Model, Type
802-2210	442210	ON2210	Ø2.25 x 10mm
802-2212	442212	ON2212	Ø2.25 x 12mm
802-2215	442215	ON2215	Ø2.25 x 15mm
802-2218	442218	ON2218	Ø2.25 x 18mm
802-2220	442220	ON2220	Ø2.25 x 20mm
802-2222	442222	ON2222	Ø2.25 x 22mm
802-2225	442225	ON2225	Ø2.25 x 25mm
802-2230	442230	ON2230	Ø2.25 x 30mm
802-2506	442506	ON2506	Ø2.5 x 6mm
802-2508	442508	ON2508	Ø2.5 x 8mm
802-2510	442510	ON2510	Ø2.5 x 10mm
802-2512	442512	ON2512	Ø2.5 x 12mm
802-2515	442515	ON2515	Ø2.5 x 15mm
802-2518	442518	ON2518	Ø2.5 x 18mm
802-2520	442520	ON2520	Ø2.5 x 20mm
802-2522	442522	ON2522	Ø2.5 x 22mm

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802-2525	442525	ON2525	Ø2.5 x 25mm
802-2530	442530	ON2530	Ø2.5 x 30mm
802-2706	442706	ON2706	Ø2.75 x 6mm
802-2708	442708	ON2708	Ø2.75 x 8mm
802-2710	442710	ON2710	Ø2.75 x 10mm
802-2712	442712	ON2712	Ø2.75 x 12mm
802-2715	442715	ON2715	Ø2.75 x 15mm
802-2718	442718	ON2718	Ø2.75 x 18mm
802-2720	442720	ON2720	Ø2.75 x 20mm
802-2722	442722	ON2722	Ø2.75 x 22mm
802-2725	442725	ON2725	Ø2.75 x 25mm
802-2730	442730	ON2730	Ø2.75 x 30mm
802-3006	443006	ON3006	Ø3.0 x 6mm
802-3008	443008	ON3008	Ø3.0 x 8mm
802-3010	443010	ON3010	Ø3.0 x 10mm
802-3012	443012	ON3012	Ø3.0 x 12mm

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802-3015	443015	ON3015	Ø3.0 x 15mm
802-3018	443018	ON3018	Ø3.0 x 18mm
802-3020	443020	ON3020	Ø3.0 x 20mm
802-3022	443022	ON3022	Ø3.0 x 22mm
802-3025	443025	ON3025	Ø3.0 x 25mm
802-3030	443030	ON3030	Ø3.0 x 30mm
802-3206	443206	ON3206	Ø3.25 x 6mm
802-3208	443208	ON3208	Ø3.25 x 8mm
802-3210	443210	ON3210	Ø3.25 x 10mm
802-3212	443212	ON3212	Ø3.25 x 12mm
802-3215	443215	ON3215	Ø3.25 x 15mm
802-3218	443218	ON3218	Ø3.25 x 18mm
802-3220	443220	ON3220	Ø3.25 x 20mm
802-3222	443222	ON3222	Ø3.25 x 22mm
802-3225	443225	ON3225	Ø3.25 x 25mm
802-3230	443230	ON3230	Ø3.25 x 30mm

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802-3506	443506	ON3506	Ø3.5 x 6mm
802-3508	443508	ON3508	Ø3.5 x 8mm
802-3510	443510	ON3510	Ø3.5 x 10mm
802-3512	443512	ON3512	Ø3.5 x 12mm
802-3515	443515	ON3515	Ø3.5 x 15mm
802-3518	443518	ON3518	Ø3.5 x 18mm
802-3520	443520	ON3520	Ø3.5 x 20mm
802-3522	443522	ON3522	Ø3.5 x 22mm
802-3525	443525	ON3525	Ø3.5 x 25mm
802-3530	443530	ON3530	Ø3.5 x 30mm
802-3706	443706	ON3706	Ø3.75 x 6mm
802-3708	443708	ON3708	Ø3.75 x 8mm
802-3710	443710	ON3710	Ø3.75 x 10mm
802-3712	443712	ON3712	Ø3.75 x 12mm
802-3715	443715	ON3715	Ø3.75 x 15mm
802-3718	443718	ON3718	Ø3.75 x 18mm

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802-3720	443720	ON3720	Ø3.75 x 20mm
802-3722	443722	ON3722	Ø3.75 x 22mm
802-3725	443725	ON3725	Ø3.75 x 25mm
802-3730	443730	ON3730	Ø3.75 x 30mm
802-4006	444006	ON4006	Ø4.0 x 6mm
802-4008	444008	ON4008	Ø4.0 x 8mm
802-4010	444010	ON4010	Ø4.0 x 10mm
802-4012	444012	ON4012	Ø4.0 x 12mm
802-4015	444015	ON4015	Ø4.0 x 15mm
802-4018	444018	ON4018	Ø4.0 x 18mm
802-4020	444020	ON4020	Ø4.0 x 20mm
802-4022	444022	ON4022	Ø4.0 x 22mm
802-4025	444025	ON4025	Ø4.0 x 25mm
802-4030	444030	ON4030	Ø4.0 x 30mm
802-4506	444506	ON4506	Ø4.5 x 6mm
802-4508	444508	ON4508	Ø4.5 x 8mm

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802-4510	444510	ON4510	Ø4.5 x 10mm
802-4512	444512	ON4512	Ø4.5 x 12mm
802-4515	444515	ON4515	Ø4.5 x 15mm
802-4518	444518	ON4518	Ø4.5 x 18mm
802-4520	444520	ON4520	Ø4.5 x 20mm
802-4522	444522	ON4522	Ø4.5 x 22mm
802-4525	444525	ON4525	Ø4.5 x 25mm
802-4530	444530	ON4530	Ø4.5 x 30mm
802-5006	445006	ON5006	Ø5.0 x 6mm
802-5008	445008	ON5008	Ø5.0 x 8mm
802-5010	445010	ON5010	Ø5.0 x 10mm
802-5012	445012	ON5012	Ø5.0 x 12mm
802-5015	445015	ON5015	Ø5.0 x 15mm
802-5018	445018	ON5018	Ø5.0 x 18mm
802-5020	445020	ON5020	Ø5.0 x 20mm
802-5022	445022	ON5022	Ø5.0 x 22mm

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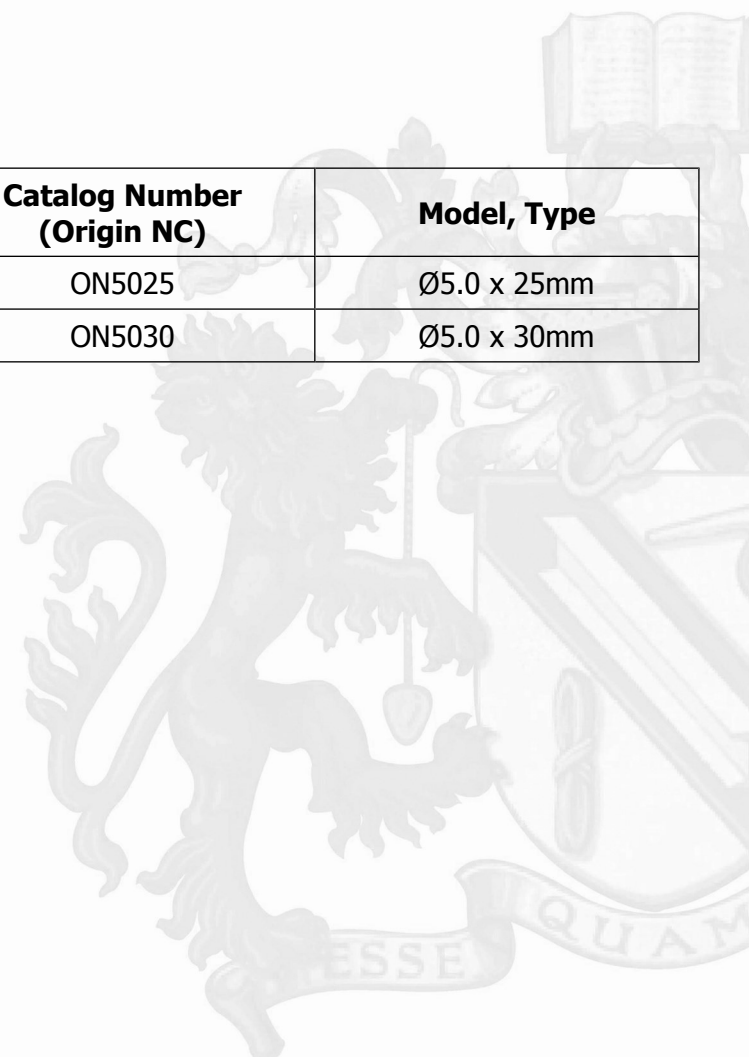
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802-5025	445025	ON5025	Ø5.0 x 25mm
802-5030	445030	ON5030	Ø5.0 x 30mm



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Certificate History

Date	Reference Number	Action
13 September 2017	8634512	First issue. Transfer from another Notified Body.
24 October 2018	9640672	Certificate Renewal.
07 February 2019	8250575	Traceable to NB 0086.
15 April 2020	8896288	Dupont Tyvek change. Administrative change on product table. Correction to history entry against reference 9640672 dated 24 October 2018 to include administrative change to product table.
Current	8861114	Addition of new sizes (balloon length 6mm, 20mm, 22mm, 25mm and 30mm). Additional of other two brand names (Aperi NC and Origin NC) and corresponding new series catalogue numbers.

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