



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13150-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : BrosMed Medical Co., Ltd

Company Address : 15th Building, SMEs Venture Park SongShan Lake Hi-Tech Industrial Development Zone Dongguan 523808, GuangDong, China

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : - Sterile Wedge NC Scoring Balloon Dilatation Catheter - Class III  
- Sterile Alveo HP Balloon Dilatation Catheter - Class III  
- Sterile Tri-Wedge PTA Scoring Balloon Dilatation Catheter - Class IIa

GMDN : 44088, 47732, 17184

Product Types are attached.

Certificate Number : M.2020.106.13150  
Report Number : MD.3952.IB  
Initial Assessment Date : 30.08.2019  
Registration Date : 20.01.2020  
Revision Date /No : -  
Expiry Date : 27.05.2024

  
UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.





UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).

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This document containing 4 (four) pages is the Annex of the Certificate with the number M.2020.106.13150 and with the registration date of 20.01.2020 issued for “BrosMed Medical Co., Ltd” by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

**Sterile Alveo HP Balloon Dilatation Catheter - Class III - 47732**

Catalog No.	Balloon Size	Catalog No.	Balloon Size
813-0705	0.75x5mm	813-1505	1.5x5mm
813-0708	0.75x8mm	813-1508	1.5x8mm
813-0710	0.75x10mm	813-1510	1.5x10mm
813-0712	0.75x12mm	813-1512	1.5x12mm
813-0715	0.75x15mm	813-1515	1.5x15mm
813-0720	0.75x20mm	813-1520	1.5x20mm
813-0725	0.75x25mm	813-1525	1.5x25mm
813-0730	0.75x30mm	813-1530	1.5x30mm
813-1005	1.0x5mm	813-1705	1.75x5mm
813-1008	1.0x8mm	813-1708	1.75x8mm
813-1010	1.0x10mm	813-1710	1.75x10mm
813-1012	1.0x12mm	813-1712	1.75x12mm
813-1015	1.0x15mm	813-1715	1.75x15mm
813-1020	1.0x20mm	813-1720	1.75x20mm
813-1025	1.0x25mm	813-1725	1.75x25mm
813-1030	1.0x30mm	813-1730	1.75x30mm
813-1205	1.25x5mm	813-2005	2.0x5mm
813-1208	1.25x8mm	813-2008	2.0x8mm
813-1210	1.25x10mm	813-2010	2.0x10mm
813-1212	1.25x12mm	813-2012	2.0x12mm
813-1215	1.25x15mm	813-2015	2.0x15mm
813-1220	1.25x20mm	813-2020	2.0x20mm
813-1225	1.25x25mm	813-2025	2.0x25mm
813-1230	1.25x30mm	813-2030	2.0x30mm

**Sterile Wedge NC Balloon Dilatation Catheter - Class III- 44088**

Catalog No.	Balloon Size	Catalog No.	Balloon Size
814-2006	2.0x6mm	814-3018	3.0x18mm
814-2008	2.0x8mm	814-3020	3.0x20mm
814-2010	2.0x10mm	814-3023	3.0x23mm
814-2012	2.0x12mm	814-3025	3.0x25mm
814-2015	2.0x15mm	814-3030	3.0x30mm
814-2018	2.0x18mm	814-3206	3.25x6mm





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814-2020	2.0x20mm	814-3208	3.25x8mm
814-2023	2.0x23mm	814-3210	3.25x10mm
814-2025	2.0x25mm	814-3212	3.25x12mm
814-2030	2.0x30mm	814-3215	3.25x15mm
814-2206	2.25x6mm	814-3218	3.25x18mm
814-2208	2.25x8mm	814-3220	3.25x20mm
814-2210	2.25x10mm	814-3223	3.25x23mm
814-2212	2.25x12mm	814-3225	3.25x25mm
814-2215	2.25x15mm	814-3230	3.25x30mm
814-2218	2.25x18mm	814-3506	3.5x6mm
814-2220	2.25x20mm	814-3508	3.5x8mm
814-2223	2.25x23mm	814-3510	3.5x10mm
814-2225	2.25x25mm	814-3512	3.5x12mm
814-2230	2.25x30mm	814-3515	3.5x15mm
814-2506	2.5x6mm	814-3518	3.5x18mm
814-2508	2.5x8mm	814-3520	3.5x20mm
814-2510	2.5x10mm	814-3523	3.5x23mm
814-2512	2.5x12mm	814-3525	3.5x25mm
814-2515	2.5x15mm	814-3530	3.5x30mm
814-2518	2.5x18mm	814-3706	3.75x6mm
814-2520	2.5x20mm	814-3708	3.75x8mm
814-2523	2.5x23mm	814-3710	3.75x10mm
814-2525	2.5x25mm	814-3712	3.75x12mm
814-2530	2.5x30mm	814-3715	3.75x15mm
814-2706	2.75x6mm	814-3718	3.75x18mm
814-2708	2.75x8mm	814-3720	3.75x20mm
814-2710	2.75x10mm	814-3723	3.75x23mm
814-2712	2.75x12mm	814-3725	3.75x25mm
814-2715	2.75x15mm	814-3730	3.75x30mm
814-2718	2.75x18mm	814-4006	4.0x6mm
814-2720	2.75x20mm	814-4008	4.0x8mm





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814-2723	2.75x23mm	814-4010	4.0x10mm
814-2725	2.75x25mm	814-4012	4.0x12mm
814-2730	2.75x30mm	814-4015	4.0x15mm
814-3006	3.0x6mm	814-4018	4.0x18mm
814-3008	3.0x8mm	814-4020	4.0x20mm
814-3010	3.0x10mm	814-4023	4.0x23mm
814-3012	3.0x12mm	814-4025	4.0x25mm
814-3015	3.0x15mm	814-4030	4.0x30mm

**Sterile Tri-Wedge PTA Scoring Balloon Dilatation Catheter - Class Ila - 17184**

Catalog No.	Balloon Size	Shaft Length	Catalog No.	Balloon Size	Shaft Length
21-18S32	3.0x20mm	50cm	21-35S32	3.0x20mm	50cm
21-18S33	3.0x30mm	50cm	21-35S33	3.0x30mm	50cm
21-18S34	3.0x40mm	50cm	21-35S34	3.0x40mm	50cm
21-18S36	3.0x60mm	50cm	21-35S36	3.0x60mm	50cm
21-18S42	4.0x20mm	50cm	21-35S42	4.0x20mm	50cm
21-18S43	4.0x30mm	50cm	21-35S43	4.0x30mm	50cm
21-18S44	4.0x40mm	50cm	21-35S44	4.0x40mm	50cm
21-18S46	4.0x60mm	50cm	21-35S46	4.0x60mm	50cm
21-18S52	5.0x20mm	50cm	21-35S52	5.0x20mm	50cm
21-18S53	5.0x30mm	50cm	21-35S53	5.0x30mm	50cm
21-18S54	5.0x40mm	50cm	21-35S54	5.0x40mm	50cm
21-18S56	5.0x60mm	50cm	21-35S56	5.0x60mm	50cm
21-18S62	6.0x20mm	50cm	21-35S62	6.0x20mm	50cm
21-18S63	6.0x30mm	50cm	21-35S63	6.0x30mm	50cm
21-18S64	6.0x40mm	50cm	21-35S64	6.0x40mm	50cm
21-18S66	6.0x60mm	50cm	21-35S66	6.0x60mm	50cm
21-18S72	7.0x20mm	50cm	21-35S72	7.0x20mm	50cm
21-18S73	7.0x30mm	50cm	21-35S73	7.0x30mm	50cm
21-18S74	7.0x40mm	50cm	21-35S74	7.0x40mm	50cm
21-18S76	7.0x60mm	50cm	21-35S76	7.0x60mm	50cm





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21-18S82	8.0x20mm	50cm	21-35S82	8.0x20mm	50cm
21-18S83	8.0x30mm	50cm	21-35S83	8.0x30mm	50cm
21-18S84	8.0x40mm	50cm	21-35S84	8.0x40mm	50cm
21-18S86	8.0x60mm	50cm	21-35S86	8.0x60mm	50cm
21-18L32	3.0x20mm	90cm	21-35L32	3.0x20mm	75cm
21-18L33	3.0x30mm	90cm	21-35L33	3.0x30mm	75cm
21-18L34	3.0x40mm	90cm	21-35L34	3.0x40mm	75cm
21-18L36	3.0x60mm	90cm	21-35L36	3.0x60mm	75cm
21-18L42	4.0x20mm	90cm	21-35L42	4.0x20mm	75cm
21-18L43	4.0x30mm	90cm	21-35L43	4.0x30mm	75cm
21-18L44	4.0x40mm	90cm	21-35L44	4.0x40mm	75cm
21-18L46	4.0x60mm	90cm	21-35L46	4.0x60mm	75cm
21-18L52	5.0x20mm	90cm	21-35L52	5.0x20mm	75cm
21-18L53	5.0x30mm	90cm	21-35L53	5.0x30mm	75cm
21-18L54	5.0x40mm	90cm	21-35L54	5.0x40mm	75cm
21-18L56	5.0x60mm	90cm	21-35L56	5.0x60mm	75cm
21-18L62	6.0x20mm	90cm	21-35L62	6.0x20mm	75cm
21-18L63	6.0x30mm	90cm	21-35L63	6.0x30mm	75cm
21-18L64	6.0x40mm	90cm	21-35L64	6.0x40mm	75cm
21-18L66	6.0x60mm	90cm	21-35L66	6.0x60mm	75cm
21-18L72	7.0x20mm	90cm	21-35L72	7.0x20mm	75cm
21-18L73	7.0x30mm	90cm	21-35L73	7.0x30mm	75cm
21-18L74	7.0x40mm	90cm	21-35L74	7.0x40mm	75cm
21-18L76	7.0x60mm	90cm	21-35L76	7.0x60mm	75cm
21-18L82	8.0x20mm	90cm	21-35L82	8.0x20mm	75cm
21-18L83	8.0x30mm	90cm	21-35L83	8.0x30mm	75cm
21-18L84	8.0x40mm	90cm	21-35L84	8.0x40mm	75cm
21-18L86	8.0x60mm	90cm	21-35L86	8.0x60mm	75cm

