

EU Declaration of Conformity

Document Number: DC-1002, rev01

Product Name: **Tiche PTA Balloon Dilatation Catheter**

Basic UDI-DI: 695848140001LR

Classification: Class IIa (Annex VIII, Regulation (EU) 2017/745)

Conformity Assessment: Chapters I, III and Section 4 of Annex IX of Regulation (EU) 2017/745

Manufacturer: Name: BrosMed Medical Co., Ltd.
SRN: CN-MF-000007501
Address: 15th Building, SMEs Venture Park
Songsan Lake Hi-Tech Industrial Development Zone
Dongguan, Guangdong, 523808, China

European Authorized Representative: Name: BrosMed Medical B.V.
SRN: NL-AR-000002616
Address: Mgr. Buckxstraat 8, 6134 AP Sittard, the Netherlands

Notified Body: Name: BSI (CE 2797)
Address: Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, The Netherlands

Referred Common Specifications: N/A

Certificate: Quality Management System Certificate No.: MDR 752504
Issue Date: 2023-03-10

General Applicable Regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council
of 5 April 2017 on Medical Device

*Under the sole responsibility of manufacturer, we hereby declare that the distributed CE marked products, as specified above and on the attached product models, are covered by the "CE Marking of Conformity Certificate", reference number: **MDR 752504**, and delivered by Notified Body BSI, Notified Body Identification Number: 2797. All products on the attached schedule meet the provisions of the mentioned above Regulation, and conform to the required technical documentation, in accordance with Annex II of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Device.*

This declaration is based on the conformity assessment as specified in Chapters I and III of Annex IX of Regulation (EU) 2017/745, and including an assessment of the technical documentation as specified in Section 4 of that Annex IX, which is confirmed in the said CE Marking of Conformity Certificate, issued and delivered by BSI.

Printed Name: _____

Title: _____

Regulatory Affairs Manager

Signature: _____

Place & Date: _____

Mar. 21. 2023

Tiche PTA Balloon Dilatation Catheter

Intended use:

The Tiche Balloon Dilatation Catheter is intended for dilatation of stenosis and post-deployed stent in the peripheral vasculature.

Product Models:

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-030240	3x20mm	40cm	34-040313	4x30mm	135cm
34-030340	3x30mm	40cm	34-040413	4x40mm	135cm
34-030440	3x40mm	40cm	34-040613	4x60mm	135cm
34-030640	3x60mm	40cm	34-040813	4x80mm	135cm
34-030840	3x80mm	40cm	34-041013	4x100mm	135cm
34-031040	3x100mm	40cm	34-041213	4x120mm	135cm
34-040240	4x20mm	40cm	34-041513	4x150mm	135cm
34-040340	4x30mm	40cm	34-041813	4x180mm	135cm
34-040440	4x40mm	40cm	34-042013	4x200mm	135cm
34-040640	4x60mm	40cm	34-050213	5x20mm	135cm
34-040840	4x80mm	40cm	34-050313	5x30mm	135cm
34-041040	4x100mm	40cm	34-050413	5x40mm	135cm
34-050240	5x20mm	40cm	34-050613	5x60mm	135cm
34-050340	5x30mm	40cm	34-050813	5x80mm	135cm
34-050440	5x40mm	40cm	34-051013	5x100mm	135cm
34-050640	5x60mm	40cm	34-051213	5x120mm	135cm
34-050840	5x80mm	40cm	34-051513	5x150mm	135cm
34-051040	5x100mm	40cm	34-051813	5x180mm	135cm
34-051240	5x120mm	40cm	34-052013	5x200mm	135cm
34-060240	6x20mm	40cm	34-060213	6x20mm	135cm
34-060340	6x30mm	40cm	34-060313	6x30mm	135cm
34-060440	6x40mm	40cm	34-060413	6x40mm	135cm
34-060640	6x60mm	40cm	34-060613	6x60mm	135cm
34-060840	6x80mm	40cm	34-060813	6x80mm	135cm
34-061040	6x100mm	40cm	34-061013	6x100mm	135cm
34-061240	6x120mm	40cm	34-061213	6x120mm	135cm
34-070240	7x20mm	40cm	34-061513	6x150mm	135cm
34-070340	7x30mm	40cm	34-061813	6x180mm	135cm
34-070440	7x40mm	40cm	34-062013	6x200mm	135cm
34-070640	7x60mm	40cm	34-070213	7x20mm	135cm
34-070840	7x80mm	40cm	34-070313	7x30mm	135cm
34-071040	7x100mm	40cm	34-070413	7x40mm	135cm
34-080240	8x20mm	40cm	34-070613	7x60mm	135cm
34-080340	8x30mm	40cm	34-070813	7x80mm	135cm
34-080440	8x40mm	40cm	34-071013	7x100mm	135cm
34-080640	8x60mm	40cm	34-071213	7x120mm	135cm
34-080840	8x80mm	40cm	34-071513	7x150mm	135cm
34-081040	8x100mm	40cm	34-071813	7x180mm	135cm
34-090240	9x20mm	40cm	34-072013	7x200mm	135cm
34-090340	9x30mm	40cm	34-080213	8x20mm	135cm
34-090440	9x40mm	40cm	34-080313	8x30mm	135cm
34-090640	9x60mm	40cm	34-080413	8x40mm	135cm
34-090840	9x80mm	40cm	34-080613	8x60mm	135cm
34-100240	10x20mm	40cm	34-080813	8x80mm	135cm
34-100340	10x30mm	40cm	34-081013	8x100mm	135cm
34-100440	10x40mm	40cm	34-081213	8x120mm	135cm
34-100640	10x60mm	40cm	34-081513	8x150mm	135cm
34-100840	10x80mm	40cm	34-081813	8x180mm	135cm
34-120240	12x20mm	40cm	34-082013	8x200mm	135cm
34-120340	12x30mm	40cm	34-090213	9x20mm	135cm

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-120440	12x40mm	40cm	34-090313	9x30mm	135cm
34-120640	12x60mm	40cm	34-090413	9x40mm	135cm
34-120840	12x80mm	40cm	34-090613	9x60mm	135cm
34-030275	3x20mm	75cm	34-090813	9x80mm	135cm
34-030375	3x30mm	75cm	34-100213	10x20mm	135cm
34-030475	3x40mm	75cm	34-100313	10x30mm	135cm
34-030675	3x60mm	75cm	34-100413	10x40mm	135cm
34-030875	3x80mm	75cm	34-100613	10x60mm	135cm
34-031075	3x100mm	75cm	34-100813	10x80mm	135cm
34-031275	3x120mm	75cm	34-120213	12x20mm	135cm
34-031575	3x150mm	75cm	34-120313	12x30mm	135cm
34-031875	3x180mm	75cm	34-120413	12x40mm	135cm
34-032075	3x200mm	75cm	34-120613	12x60mm	135cm
34-040275	4x20mm	75cm	34-120813	12x80mm	135cm
34-040375	4x30mm	75cm	34-030212	3x20mm	120cm
34-040475	4x40mm	75cm	34-030312	3x30mm	120cm
34-040675	4x60mm	75cm	34-030412	3x40mm	120cm
34-040875	4x80mm	75cm	34-030612	3x60mm	120cm
34-041075	4x100mm	75cm	34-030812	3x80mm	120cm
34-041275	4x120mm	75cm	34-031012	3x100mm	120cm
34-041575	4x150mm	75cm	34-031212	3x120mm	120cm
34-041875	4x180mm	75cm	34-031512	3x150mm	120cm
34-042075	4x200mm	75cm	34-031812	3x180mm	120cm
34-050275	5x20mm	75cm	34-032012	3x200mm	120cm
34-050375	5x30mm	75cm	34-040212	4x20mm	120cm
34-050475	5x40mm	75cm	34-040312	4x30mm	120cm
34-050675	5x60mm	75cm	34-040412	4x40mm	120cm
34-050875	5x80mm	75cm	34-040612	4x60mm	120cm
34-051075	5x100mm	75cm	34-040812	4x80mm	120cm
34-051275	5x120mm	75cm	34-041012	4x100mm	120cm
34-051575	5x150mm	75cm	34-041212	4x120mm	120cm
34-051875	5x180mm	75cm	34-041512	4x150mm	120cm
34-052075	5x200mm	75cm	34-041812	4x180mm	120cm
34-060275	6x20mm	75cm	34-042012	4x200mm	120cm
34-060375	6x30mm	75cm	34-050212	5x20mm	120cm
34-060475	6x40mm	75cm	34-050312	5x30mm	120cm
34-060675	6x60mm	75cm	34-050412	5x40mm	120cm
34-060875	6x80mm	75cm	34-050612	5x60mm	120cm
34-061075	6x100mm	75cm	34-050812	5x80mm	120cm
34-061275	6x120mm	75cm	34-051012	5x100mm	120cm
34-061575	6x150mm	75cm	34-051212	5x120mm	120cm
34-061875	6x180mm	75cm	34-051512	5x150mm	120cm
34-062075	6x200mm	75cm	34-051812	5x180mm	120cm
34-070275	7x20mm	75cm	34-052012	5x200mm	120cm
34-070375	7x30mm	75cm	34-060212	6x20mm	120cm
34-070475	7x40mm	75cm	34-060312	6x30mm	120cm
34-070675	7x60mm	75cm	34-060412	6x40mm	120cm
34-070875	7x80mm	75cm	34-060612	6x60mm	120cm
34-071075	7x100mm	75cm	34-060812	6x80mm	120cm
34-071275	7x120mm	75cm	34-061012	6x100mm	120cm
34-071575	7x150mm	75cm	34-061212	6x120mm	120cm
34-071875	7x180mm	75cm	34-061512	6x150mm	120cm
34-072075	7x200mm	75cm	34-061812	6x180mm	120cm
34-080275	8x20mm	75cm	34-062012	6x200mm	120cm
34-080375	8x30mm	75cm	34-070212	7x20mm	120cm
34-080475	8x40mm	75cm	34-070312	7x30mm	120cm
34-080675	8x60mm	75cm	34-070412	7x40mm	120cm
34-080875	8x80mm	75cm	34-070612	7x60mm	120cm

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-081075	8x100mm	75cm	34-070812	7x80mm	120cm
34-081275	8x120mm	75cm	34-071012	7x100mm	120cm
34-081575	8x150mm	75cm	34-071212	7x120mm	120cm
34-081875	8x180mm	75cm	34-071512	7x150mm	120cm
34-082075	8x200mm	75cm	34-071812	7x180mm	120cm
34-090275	9x20mm	75cm	34-072012	7x200mm	120cm
34-090375	9x30mm	75cm	34-080212	8x20mm	120cm
34-090475	9x40mm	75cm	34-080312	8x30mm	120cm
34-090675	9x60mm	75cm	34-080412	8x40mm	120cm
34-090875	9x80mm	75cm	34-080612	8x60mm	120cm
34-100275	10x20mm	75cm	34-080812	8x80mm	120cm
34-100375	10x30mm	75cm	34-081012	8x100mm	120cm
34-100475	10x40mm	75cm	34-081212	8x120mm	120cm
34-100675	10x60mm	75cm	34-081512	8x150mm	120cm
34-100875	10x80mm	75cm	34-081812	8x180mm	120cm
34-120275	12x20mm	75cm	34-082012	8x200mm	120cm
34-120375	12x30mm	75cm	34-090212	9x20mm	120cm
34-120475	12x40mm	75cm	34-090312	9x30mm	120cm
34-120675	12x60mm	75cm	34-090412	9x40mm	120cm
34-120875	12x80mm	75cm	34-090612	9x60mm	120cm
34-030213	3x20mm	135cm	34-090812	9x80mm	120cm
34-030313	3x30mm	135cm	34-100212	10x20mm	120cm
34-030413	3x40mm	135cm	34-100312	10x30mm	120cm
34-030613	3x60mm	135cm	34-100412	10x40mm	120cm
34-030813	3x80mm	135cm	34-100612	10x60mm	120cm
34-031013	3x100mm	135cm	34-100812	10x80mm	120cm
34-031213	3x120mm	135cm	34-120212	12x20mm	120cm
34-031513	3x150mm	135cm	34-120312	12x30mm	120cm
34-031813	3x180mm	135cm	34-120412	12x40mm	120cm
34-032013	3x200mm	135cm	34-120612	12x60mm	120cm
34-040213	4x20mm	135cm	34-120812	12x80mm	120cm

/LOGO/

Patvirtinimo deklaracija

Dokumento numeris: DC-1022, rev01

Produkto pavadinimas: Tiche PTA balioninis diliatacinis kateteris

Pagrindinis UDI-DI: 695848140001LR

Klasifikacija: IIa klasė (Reglamento (ES) 2017/745 VIII priedas) Reglamento (ES) 2017/745 I

Konformijinis vertinimas: III skyriaus ir IX priedo 4 skirsnis Pavadinimas: BrosMed Medical Co., Ltd.

Gamintojas: Pavadinimas: BrosMed Medical Co., Ltd.

SRN: NL-AR-000002616

Adresas: **15th Building, SMEs Venture Park
Songshan Lake Hi-Tech Industrial Development Zone
Dongguan, Guangdong, 523808, China**

Europos įgaliotasis atstovas: Pavadinimas: BrosMed Medical B.V.

SRN: NL-AR-000002616

Adresas: **Mgr. Buckxstraat 8, 6134 AP Sittard, the Netherlands**

Notifikuota įstaiga: Pavadinimas: BSI (CE 2797)

Adresas: **Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, The Netherlands**

Nurodytos bendrosios specifikacijos: N/A

Sertifikatas: Kokybės vadybos sistemos sertifikato Nr.: MDR 752504

Išdavimo data: 2023-03-10

Bendrieji taikytini teisės aktai: 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamentas (ES) 2017/745 dėl medicinos prietaisų.

Gamintojas prisiima visą atsakomybę ir pareiškia, kad aukščiau ir pridedamuose gaminių modeliuose nurodytiems CE ženklų pažymėtiems gaminiams yra suteiktas "CE atitikties ženklo sertifikatas", nuorodos numeris: MDR 752504, kurį pateikė notifikuotoji įstaiga BSI, notifikuotosios įstaigos identifikacinis numeris. 2797. Visi pridedamame sąraše esantys gaminiai atitinka minėto reglamento nuostatas ir atitinka reikalaujamus techninius dokumentus pagal 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/745 dėl medicinos prietaisų II priedą.

Ši deklaracija grindžiama atitikties įvertinimu, kaip nurodyta Reglamento (ES) 2017/745 IX priedo I ir III skyriuose, įskaitant techninės dokumentacijos įvertinimą, kaip nurodyta IX priedo 4 skirsnyje, kuris patvirtintas minėtu CE atitikties ženklo sertifikatu, kurį išdavė ir pateikė BSI.

/Vardas/

/Pareigos/

/Parašas/

/Vieta, laikas/

Tiche PTA Balloon Dilatation Catheter

Numatytas naudojimas:

Tiche balioninis dilatacinis kateteris skirtas stenozeis dilatuoti ir stentams po dilatacijos periferinėse kraujagyslėse uždėti.

Product Models:

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-030240	3x20mm	40cm	34-040313	4x30mm	135cm
34-030340	3x30mm	40cm	34-040413	4x40mm	135cm
34-030440	3x40mm	40cm	34-040613	4x60mm	135cm
34-030640	3x60mm	40cm	34-040813	4x80mm	135cm
34-030840	3x80mm	40cm	34-041013	4x100mm	135cm
34-031040	3x100mm	40cm	34-041213	4x120mm	135cm
34-040240	4x20mm	40cm	34-041513	4x150mm	135cm
34-040340	4x30mm	40cm	34-041813	4x180mm	135cm
34-040440	4x40mm	40cm	34-042013	4x200mm	135cm
34-040640	4x60mm	40cm	34-050213	5x20mm	135cm
34-040840	4x80mm	40cm	34-050313	5x30mm	135cm
34-041040	4x100mm	40cm	34-050413	5x40mm	135cm
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34-051040	5x100mm	40cm	34-051813	5x180mm	135cm
34-051240	5x120mm	40cm	34-052013	5x200mm	135cm
34-060240	6x20mm	40cm	34-060213	6x20mm	135cm
34-060340	6x30mm	40cm	34-060313	6x30mm	135cm
34-060440	6x40mm	40cm	34-060413	6x40mm	135cm
34-060640	6x60mm	40cm	34-060613	6x60mm	135cm
34-060840	6x80mm	40cm	34-060813	6x80mm	135cm
34-061040	6x100mm	40cm	34-061013	6x100mm	135cm
34-061240	6x120mm	40cm	34-061213	6x120mm	135cm
34-070240	7x20mm	40cm	34-061513	6x150mm	135cm
34-070340	7x30mm	40cm	34-061813	6x180mm	135cm
34-070440	7x40mm	40cm	34-062013	6x200mm	135cm
34-070640	7x60mm	40cm	34-070213	7x20mm	135cm
34-070840	7x80mm	40cm	34-070313	7x30mm	135cm
34-071040	7x100mm	40cm	34-070413	7x40mm	135cm
34-080240	8x20mm	40cm	34-070613	7x60mm	135cm
34-080340	8x30mm	40cm	34-070813	7x80mm	135cm
34-080440	8x40mm	40cm	34-071013	7x100mm	135cm
34-080640	8x60mm	40cm	34-071213	7x120mm	135cm
34-080840	8x80mm	40cm	34-071513	7x150mm	135cm
34-081040	8x100mm	40cm	34-071813	7x180mm	135cm
34-090240	9x20mm	40cm	34-072013	7x200mm	135cm
34-090340	9x30mm	40cm	34-080213	8x20mm	135cm
34-090440	9x40mm	40cm	34-080313	8x30mm	135cm
34-090640	9x60mm	40cm	34-080413	8x40mm	135cm
34-090840	9x80mm	40cm	34-080613	8x60mm	135cm
34-100240	10x20mm	40cm	34-080813	8x80mm	135cm
34-100340	10x30mm	40cm	34-081013	8x100mm	135cm
34-100440	10x40mm	40cm	34-081213	8x120mm	135cm
34-100640	10x60mm	40cm	34-081513	8x150mm	135cm
34-100840	10x80mm	40cm	34-081813	8x180mm	135cm
34-120240	12x20mm	40cm	34-082013	8x200mm	135cm
34-120340	12x30mm	40cm	34-090213	9x20mm	135cm

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-120440	12x40mm	40cm	34-090313	9x30mm	135cm
34-120640	12x60mm	40cm	34-090413	9x40mm	135cm
34-120840	12x80mm	40cm	34-090613	9x60mm	135cm
34-030275	3x20mm	75cm	34-090813	9x80mm	135cm
34-030375	3x30mm	75cm	34-100213	10x20mm	135cm
34-030475	3x40mm	75cm	34-100313	10x30mm	135cm
34-030675	3x60mm	75cm	34-100413	10x40mm	135cm
34-030875	3x80mm	75cm	34-100613	10x60mm	135cm
34-031075	3x100mm	75cm	34-100813	10x80mm	135cm
34-031275	3x120mm	75cm	34-120213	12x20mm	135cm
34-031575	3x150mm	75cm	34-120313	12x30mm	135cm
34-031875	3x180mm	75cm	34-120413	12x40mm	135cm
34-032075	3x200mm	75cm	34-120613	12x60mm	135cm
34-040275	4x20mm	75cm	34-120813	12x80mm	135cm
34-040375	4x30mm	75cm	34-030212	3x20mm	120cm
34-040475	4x40mm	75cm	34-030312	3x30mm	120cm
34-040675	4x60mm	75cm	34-030412	3x40mm	120cm
34-040875	4x80mm	75cm	34-030612	3x60mm	120cm
34-041075	4x100mm	75cm	34-030812	3x80mm	120cm
34-041275	4x120mm	75cm	34-031012	3x100mm	120cm
34-041575	4x150mm	75cm	34-031212	3x120mm	120cm
34-041875	4x180mm	75cm	34-031512	3x150mm	120cm
34-042075	4x200mm	75cm	34-031812	3x180mm	120cm
34-050275	5x20mm	75cm	34-032012	3x200mm	120cm
34-050375	5x30mm	75cm	34-040212	4x20mm	120cm
34-050475	5x40mm	75cm	34-040312	4x30mm	120cm
34-050675	5x60mm	75cm	34-040412	4x40mm	120cm
34-050875	5x80mm	75cm	34-040612	4x60mm	120cm
34-051075	5x100mm	75cm	34-040812	4x80mm	120cm
34-051275	5x120mm	75cm	34-041012	4x100mm	120cm
34-051575	5x150mm	75cm	34-041212	4x120mm	120cm
34-051875	5x180mm	75cm	34-041512	4x150mm	120cm
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34-060675	6x60mm	75cm	34-050412	5x40mm	120cm
34-060875	6x80mm	75cm	34-050612	5x60mm	120cm
34-061075	6x100mm	75cm	34-050812	5x80mm	120cm
34-061275	6x120mm	75cm	34-051012	5x100mm	120cm
34-061575	6x150mm	75cm	34-051212	5x120mm	120cm
34-061875	6x180mm	75cm	34-051512	5x150mm	120cm
34-062075	6x200mm	75cm	34-051812	5x180mm	120cm
34-070275	7x20mm	75cm	34-052012	5x200mm	120cm
34-070375	7x30mm	75cm	34-060212	6x20mm	120cm
34-070475	7x40mm	75cm	34-060312	6x30mm	120cm
34-070675	7x60mm	75cm	34-060412	6x40mm	120cm
34-070875	7x80mm	75cm	34-060612	6x60mm	120cm
34-071075	7x100mm	75cm	34-060812	6x80mm	120cm
34-071275	7x120mm	75cm	34-061012	6x100mm	120cm
34-071575	7x150mm	75cm	34-061212	6x120mm	120cm
34-071875	7x180mm	75cm	34-061512	6x150mm	120cm
34-072075	7x200mm	75cm	34-061812	6x180mm	120cm
34-080275	8x20mm	75cm	34-062012	6x200mm	120cm
34-080375	8x30mm	75cm	34-070212	7x20mm	120cm
34-080475	8x40mm	75cm	34-070312	7x30mm	120cm
34-080675	8x60mm	75cm	34-070412	7x40mm	120cm
34-080875	8x80mm	75cm	34-070612	7x60mm	120cm

Catalog No.	Balloon Size	Catheter Length	Catalog No.	Balloon Size	Catheter Length
34-081075	8x100mm	75cm	34-070812	7x80mm	120cm
34-081275	8x120mm	75cm	34-071012	7x100mm	120cm
34-081575	8x150mm	75cm	34-071212	7x120mm	120cm
34-081875	8x180mm	75cm	34-071512	7x150mm	120cm
34-082075	8x200mm	75cm	34-071812	7x180mm	120cm
34-090275	9x20mm	75cm	34-072012	7x200mm	120cm
34-090375	9x30mm	75cm	34-080212	8x20mm	120cm
34-090475	9x40mm	75cm	34-080312	8x30mm	120cm
34-090675	9x60mm	75cm	34-080412	8x40mm	120cm
34-090875	9x80mm	75cm	34-080612	8x60mm	120cm
34-100275	10x20mm	75cm	34-080812	8x80mm	120cm
34-100375	10x30mm	75cm	34-081012	8x100mm	120cm
34-100475	10x40mm	75cm	34-081212	8x120mm	120cm
34-100675	10x60mm	75cm	34-081512	8x150mm	120cm
34-100875	10x80mm	75cm	34-081812	8x180mm	120cm
34-120275	12x20mm	75cm	34-082012	8x200mm	120cm
34-120375	12x30mm	75cm	34-090212	9x20mm	120cm
34-120475	12x40mm	75cm	34-090312	9x30mm	120cm
34-120675	12x60mm	75cm	34-090412	9x40mm	120cm
34-120875	12x80mm	75cm	34-090612	9x60mm	120cm
34-030213	3x20mm	135cm	34-090812	9x80mm	120cm
34-030313	3x30mm	135cm	34-100212	10x20mm	120cm
34-030413	3x40mm	135cm	34-100312	10x30mm	120cm
34-030613	3x60mm	135cm	34-100412	10x40mm	120cm
34-030813	3x80mm	135cm	34-100612	10x60mm	120cm
34-031013	3x100mm	135cm	34-100812	10x80mm	120cm
34-031213	3x120mm	135cm	34-120212	12x20mm	120cm
34-031513	3x150mm	135cm	34-120312	12x30mm	120cm
34-031813	3x180mm	135cm	34-120412	12x40mm	120cm
34-032013	3x200mm	135cm	34-120612	12x60mm	120cm
34-040213	4x20mm	135cm	34-120812	12x80mm	120cm

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752504 R000

Manufacturer: Brosmed Medical Co., Ltd

Address:

15th Building
SMEs Venture Park
SongShan Lake Hi-Tech
Industrial Development Zone
Dongguan
Guangdong
523808
China

Single Registration Number: CN-MF-000007501

EU Authorised Representative: BrosMed Medical B.V.

Address:

Mgr. Buckxstraat 8
6134 AP Sittard
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):


Senior Vice President Medical Devices

First Issue Date: **2023-03-10**

Current Issue Date: **2023-03-10**

Starting Validity Date: **2023-03-10**

Expiry Date: **2028-03-09**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752504 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
PTA Balloon Dilatation Catheters	Class IIa



First Issue Date: **2023-03-10**

Current Issue Date: **2023-03-10**

Starting Validity Date: **2023-03-10**

Expiry Date: **2028-03-09**

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Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752504 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3479674	Issued



First Issue Date: **2023-03-10**

Current Issue Date: **2023-03-10**

Starting Validity Date: **2023-03-10**

Expiry Date: **2028-03-09**

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Page 3 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

ES kokybės valdymo sistemos sertifikatas

Reglamento (ES) 2017/745 IX priedo I ir III skyrius.

MDR 752504 R000

Gamintojas: Brosmed Medical Co., Ltd

Adresas:

15th Building
SMEs Venture Park
SongShan Lake Hi-Tech
Industrial Development Zone
Dongguan
Guangdong
523808
China

Vienas registracijos numeris: CN-MF-000007501

ES įgaliotasis atstovas: BrosMed Medical B.V.

Adresas:

Mgr. Buckxstraat 8
6134 AP Sittard
The Netherlands

Apimtis: Žr. pridedamą **prietaisų grafiką**.

Remiantis mūsų atliktu kokybės sistemos patikrinimu pagal Reglamento (ES) 2017/745 IX priedo I ir III skyrius, kokybės sistema atitinka reglamento reikalavimus. Pateikiant rinkai III klasės prietaisus ir IIb klasės implantuojamus prietaisus, kurie nelaikomi nusistovėjusiomis technologijomis, kaip nurodyta 52 straipsnio 4 dalyje, reikalingas papildomas IX priedo II skyriaus sertifikatas.

BSI, pirmiau nurodyto reglamento notifikuotosios įstaigos (notifikuotosios įstaigos numeris 2797), vardu ir interesais:

/PARAŠAS/

Graeme Tunbridge, vyresnysis medicinos prietaisų viceprezidentas

Pirmojo leidimo data: 2023-03-10

Galiojimo pradžios data: 2023-03-10

Dabartinio leidimo data: 2023-03-10

Galiojimo data: 2028-03-09

ES kokybės valdymo sistemos sertifikatas

Reglamento (ES) 2017/745 IX priedo I ir III skyrius.

MDR 752504 R000

Produktas: Ila klasė, pagal užsakymą pagaminti ir kiti prietaisai

Produktas PTA balioninis diliatacinis kateteris.

Rizikos klasifikavimas: klasė Ila.

Pirmojo leidimo data: 2023-03-10

Galiojimo pradžios data: 2023-03-10

Dabartinio leidimo data: 2023-03-10

Galiojimo data: 2028-03-09

ES kokybės valdymo sistemos sertifikatas

Reglamento (ES) 2017/745 IX priedo I ir III skyrius.

MDR 752504 R000

Sertifikato istorija:

Data: Dabartinė

Nuorodos numeris: 3479674

Išduotas leidimas veikti.

Pirmojo leidimo data: 2023-03-10

Galiojimo pradžios data: 2023-03-10

Dabartinio leidimo data: 2023-03-10

Galiojimo data: 2028-03-09