



CERTIFICATE

EC Certificate No. **1434-MDD-513/2019**

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Micro Science Medical AG

Meisenweg 5, 75443 Oetisheim, Germany

for the design, manufacture and final inspection of

medical devices, class IIb:

MSM PEBAS

PTA Stent System

The list of medical devices covered by this certificate is given in the Annex 1 to the Certificate

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from **2019-10-15** to **2024-05-27**

The date of issue of the Certificate: **2019-10-15**



Application No: **125/2019**
Module **H**


Anna Wyroba
Vice-President



ANNEX No 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-513/2019**

PEBAS – product table

PES0418075	PES0428075	PES0438075	PES0458075	PES0478075
PES0518075	PES0528075	PES0538075	PES0558075	PES0578075
PES0618075	PES0628075	PES0638075	PES0658075	PES0678075
PES0718075	PES0728075	PES0738075	PES0758075	PES0778075
PES0818075	PES0828075	PES0838075	PES0858075	PES0878075
PES0918075	PES0928075	PES0938075	PES0958075	PES0978075
PES1018075	PES1028075	PES1038075	PES1058075	PES1078075
PES1118075	PES1128075	PES1138075	PES1158075	PES1178075
PES1218075	PES1228075	PES1238075	PES1258075	PES1278075

PES0418115	PES0428115	PES0438115	PES0458115	PES0478115
PES0518115	PES0528115	PES0538115	PES0558115	PES0578115
PES0618115	PES0628115	PES0638115	PES0658115	PES0678115
PES0718115	PES0728115	PES0738115	PES0758115	PES0778115
PES0818115	PES0828115	PES0838115	PES0858115	PES0878115
PES0918115	PES0928115	PES0938115	PES0958115	PES0978115
PES1018115	PES1028115	PES1038115	PES1058115	PES1078115
PES1118115	PES1128115	PES1138115	PES1158115	PES1178115
PES1218115	PES1228115	PES1238115	PES1258115	PES1278115

PES0418150	PES0428150	PES0438150	PES0458150	PES0478150
PES0518150	PES0528150	PES0538150	PES0558150	PES0578150
PES0618150	PES0628150	PES0638150	PES0658150	PES0678150
PES0718150	PES0728150	PES0738150	PES0758150	PES0778150
PES0818150	PES0828150	PES0838150	PES0858150	PES0878150
PES0918150	PES0928150	PES0938150	PES0958150	PES0978150
PES1018150	PES1028150	PES1038150	PES1058150	PES1078150
PES1118150	PES1128150	PES1138150	PES1158150	PES1178150
PES1218150	PES1228150	PES1238150	PES1258150	PES1278150



Anna Wyroba
Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-518/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Micro Science Medical AG

Meisenweg 5, 75443 Oetisheim, Germany

for the design, manufacture and final inspection of

medical devices, class III

MSM ProNuPrime

Balloon Expandable Coronary Stent System

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-10-15 to 2024-05-27

The date of issue of the Certificate: 2019-10-15



Application No: 126/2019
Module H


Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-517/2019

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Micro Science Medical AG

Meisenweg 5, 75443 Oetisheim, Germany

related to the medical device, class III

MSM ProNuPrime

Balloon Expandable Coronary Stent System

The list of medical devices covered by this certificate is given in the Annex 1 to the Certificate

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-10-15 to 2024-05-27

The date of issue of the Certificate: 2019-10-15



Application No: 126/2019

Module H


Anna Wyroba
Vice-President



ANNEX No. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-517/2019**

ProNuPrime – product table

PNP20008	PNP20010	PNP20013	PNP20016
PNP22508	PNP22510	PNP22513	PNP22516
PNP25008	PNP25010	PNP25013	PNP25016
PNP27508	PNP27510	PNP27513	PNP27516
PNP30008	PNP30010	PNP30013	PNP30016
PNP32508	PNP32510	PNP32513	PNP32516
PNP35008	PNP35010	PNP35013	PNP35016
PNP40008	PNP40010	PNP40013	PNP40016

PNP20018	PNP20023	PNP20028	PNP20033
PNP22518	PNP22523	PNP22528	PNP22533
PNP25018	PNP25023	PNP25028	PNP25033
PNP27518	PNP27523	PNP27528	PNP27533
PNP30018	PNP30023	PNP30028	PNP30033
PNP32518	PNP32523	PNP32528	PNP32533
PNP35018	PNP35023	PNP35028	PNP35033
PNP40018	PNP40023	PNP40028	PNP40033

PNP20038	PNP20043	PNP20048
PNP22538	PNP22543	PNP22548
PNP25038	PNP25043	PNP25048
PNP27538	PNP27543	PNP27548
PNP30038	PNP30043	PNP30048
PNP32538	PNP32543	PNP32548
PNP35038	PNP35043	PNP35048
PNP40038	PNP40043	PNP40048



Anna Wyroba
Anna Wyroba
Vice-President



CERTIFICATE

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Micro Science Medical AG

Meisenweg 5, 75443 Oetisheim, Germany

for the design, manufacture and final inspection of

medical devices, class III

MSM PTCA Balloon

RX PTCA Balloon Catheter with Hydrophilic Coating

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-10-15 to 2024-05-27

The date of issue of the Certificate: 2019-10-15



Application No: 127/2019
Module H


Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. **1434-MDD-515/2019**

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Micro Science Medical AG

Meisenweg 5, 75443 Oetisheim, Germany

related to the medical device, class III

MSM PTCA Balloon

RX PTCA Balloon Catheter with Hydrophilic Coating

The list of medical devices covered by this certificate is given in the Annex 1 to the Certificate

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from **2019-10-15** to **2024-05-27**

The date of issue of the Certificate: **2019-10-15**



Application No: **127/2019**

Module H


Anna Wyroba
Vice-President



ANNEX No. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

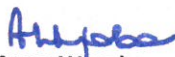
No **1434-MDD-515/2019**

PTCA Balloon – product table

PTCA15010	PTCA15015	PTCA15020	PTCA15025	PTCA15030
PTCA17510	PTCA17515	PTCA17520	PTCA17525	PTCA17530
PTCA20010	PTCA20015	PTCA20020	PTCA20025	PTCA20030
PTCA22510	PTCA22515	PTCA22520	PTCA22525	PTCA22530
PTCA25010	PTCA25015	PTCA25020	PTCA25025	PTCA25030
PTCA27510	PTCA27515	PTCA27520	PTCA27525	PTCA27530
PTCA30010	PTCA30015	PTCA30020	PTCA30025	PTCA30030
PTCA32510	PTCA32515	PTCA32520	PTCA32525	PTCA32530
PTCA35010	PTCA35015	PTCA35020	PTCA35025	PTCA35030
PTCA40010	PTCA40015	PTCA40020	PTCA40025	PTCA40030

PTCA15035	PTCA15040	PTCA15045	PTCA15050
PTCA17535	PTCA17540	PTCA17545	PTCA17550
PTCA20035	PTCA20040	PTCA20045	PTCA20050
PTCA22535	PTCA22540	PTCA22545	PTCA22550
PTCA25035	PTCA25040	PTCA25045	PTCA25050
PTCA27535	PTCA27540	PTCA27545	PTCA27550
PTCA30035	PTCA30040	PTCA30045	PTCA30050
PTCA32535	PTCA32540	PTCA32545	PTCA32550
PTCA35035	PTCA35040	PTCA35045	PTCA35050
PTCA40035	PTCA40040	PTCA40045	PTCA40050




Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. **1434-MDD-514/2019**
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Micro Science Medical AG
Meisenweg 5, 75443 Oetisheim, Germany

for the design, manufacture and final inspection of

medical devices, class IIb

MSM SENIS

Peripheral Self-expandable Stent System

The list of medical devices covered by this certificate is given in the Annex 1 to the Certificate

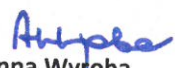
complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from **2019-10-15** to **2024-05-27**

The date of issue of the Certificate: **2019-10-15**



Application No: **128/2019**
Module H


Anna Wyroba
Vice-President



ANNEX No 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-514/2019**

SENIS – product table

NIT04020085	NIT04030085	NIT04040085	NIT04060085	NIT04080085	NIT04100085
NIT05020085	NIT05030085	NIT05040085	NIT05060085	NIT05080085	NIT05100085
NIT06020085	NIT06030085	NIT06040085	NIT06060085	NIT06080085	NIT06100085
NIT07020085	NIT07030085	NIT07040085	NIT07060085	NIT07080085	NIT07100085
NIT08020085	NIT08030085	NIT08040085	NIT08060085	NIT08080085	NIT08100085
NIT09020085	NIT09030085	NIT09040085	NIT09060085	NIT09080085	NIT09100085
NIT10020085	NIT10030085	NIT10040085	NIT10060085	NIT10080085	NIT10100085
NIT12020085	NIT12030085	NIT12040085	NIT12060085	NIT12080085	

NIT04020135	NIT04030135	NIT04040135	NIT04060135	NIT04080135	NIT04100135
NIT05020135	NIT05030135	NIT05040135	NIT05060135	NIT05080135	NIT05100135
NIT06020135	NIT06030135	NIT06040135	NIT06060135	NIT06080135	NIT06100135
NIT07020135	NIT07030135	NIT07040135	NIT07060135	NIT07080135	NIT07100135
NIT08020135	NIT08030135	NIT08040135	NIT08060135	NIT08080135	NIT08100135
NIT09020135	NIT09030135	NIT09040135	NIT09060135	NIT09080135	NIT09100135
NIT10020135	NIT10030135	NIT10040135	NIT10060135	NIT10080135	NIT10100135
NIT12020135	NIT12030135	NIT12040135	NIT12060135	NIT12080135	



Anna Wyroba
Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-510/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Micro Science Medical AG

Meisenweg 5, Oetisheim, 75443 Germany

for the design, manufacture and final inspection of

medical devices, class IIa

Peripheral Balloon Catheter

Brand name: MSM PTA Balloon & MSM BTK

The list of medical devices covered by this certificate is given in the Annexes 1, 2, 3 to the Certificate

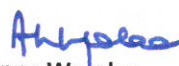
complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from **2019-10-15** to **2024-05-27**

The date of issue of the Certificate: **2019-10-15**



Application No: 122/2019
Module H


Anna Wyroba
Vice-President



ANNEX No 3 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-510/2019**

PTA Balloon– product table

BP04020085	BP04030085	BP04040085	BP04060085	BP04080085
BP05020085	BP05030085	BP05040085	BP05060085	BP05080085
BP06020085	BP06030085	BP06040085	BP06060085	BP06080085
BP07020085	BP07030085	BP07040085	BP07060085	BP07080085
BP08020085	BP08030085	BP08040085	BP08060085	BP08080085
BP09020085	BP09030085	BP09040085	BP09060085	BP09080085
BP10020085	BP10030085	BP10040085	BP10060085	BP10080085
BP12020085	BP12030085	BP12040085	BP12060085	BP12080085

BP04100085	BP04120085	BP04150085	BP04170085	BP04200085
BP05100085	BP05120085	BP05150085	BP05170085	BP05200085
BP06100085	BP06120085	BP06150085	BP06170085	BP06200085
BP07100085	BP07120085	BP07150085	BP07170085	BP07200085
BP08100085	BP08120085	BP08150085	BP08170085	BP08200085

BP04020135	BP04030135	BP04040135	BP04060135	BP04080135
BP05020135	BP05030135	BP05040135	BP05060135	BP05080135
BP06020135	BP06030135	BP06040135	BP06060135	BP06080135
BP07020135	BP07030135	BP07040135	BP07060135	BP07080135
BP08020135	BP08030135	BP08040135	BP08060135	BP08080135
BP09020135	BP09030135	BP09040135	BP09060135	BP09080135
BP10020135	BP10030135	BP10040135	BP10060135	BP10080135
BP12020135	BP12030135	BP12040135	BP12060135	BP12080135

BP04100135	BP04120135	BP04150135	BP04170135	BP04200135
BP05100135	BP05120135	BP05150135	BP05170135	BP05200135
BP06100135	BP06120135	BP06150135	BP06170135	BP06200135
BP07100135	BP07120135	BP07150135	BP07170135	BP07200135
BP08100135	BP08120135	BP08150135	BP08170135	BP08200135



Anna Wyroba
Anna Wyroba
Vice-President



ANNEX No 2 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-510/2019**

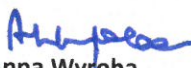
BTK – product table

BTK020080135	BTK020120135	BTK020150135
BTK025080135	BTK025120135	BTK025150135
BTK030080135	BTK030120135	BTK030150135
BTK040080135	BTK040120135	BTK040150135
BTK050080135	BTK050120135	BTK050150135

BTK020020150	BTK020030150	BTK020040150	BTK020060150
BTK025020150	BTK025030150	BTK025040150	BTK025060150
BTK030020150	BTK030030150	BTK030040150	BTK030060150
BTK040020150	BTK040030150	BTK040040150	BTK040060150
BTK050020150	BTK050030150	BTK050040150	BTK050060150

BTK020080150	BTK020120150	BTK020150150
BTK025080150	BTK025120150	BTK025150150
BTK030080150	BTK030120150	BTK030150150
BTK040080150	BTK040120150	BTK040150150
BTK050080150	BTK050120150	BTK050150150




Anna Wyroba
Vice-President



ANNEX No 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-510/2019

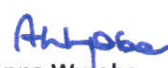
BTK – product table

BTK020020085	BTK020030085	BTK020040085	BTK020060085
BTK025020085	BTK025030085	BTK025040085	BTK025060085
BTK030020085	BTK030030085	BTK030040085	BTK030060085
BTK040020085	BTK040030085	BTK040040085	BTK040060085
BTK050020085	BTK050030085	BTK050040085	BTK050060085

BTK020080085	BTK020120085	BTK020150085
BTK025080085	BTK025120085	BTK025150085
BTK030080085	BTK030120085	BTK030150085
BTK040080085	BTK040120085	BTK040150085
BTK050080085	BTK050120085	BTK050150085

BTK020020135	BTK020030135	BTK020040135	BTK020060135
BTK025020135	BTK025030135	BTK025040135	BTK025060135
BTK030020135	BTK030030135	BTK030040135	BTK030060135
BTK040020135	BTK040030135	BTK040040135	BTK040060135
BTK050020135	BTK050030135	BTK050040135	BTK050060135




Anna Wyroba
Vice-President