



CERTIFICATE

EC Certificate No. 1434-MDD-519/2019
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 DES Sirolimus

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: 124/2019

Module H


Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-520/2019
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 DES Sirolimus
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: 124/2019

Module H


Anna Wyroba
Vice-President



ANNEX No 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-519/2019

DES Sirolimus – product table

DES20008	DES20010	DES20013	DES20016
DES22508	DES22510	DES22513	DES22516
DES25008	DES25010	DES25013	DES25016
DES27508	DES27510	DES27513	DES27516
DES30008	DES30010	DES30013	DES30016
DES32508	DES32510	DES32513	DES32516
DES35008	DES35010	DES35013	DES35016
DES40008	DES40010	DES40013	DES40016

DES20018	DES20023	DES20028	DES20033
DES22518	DES22523	DES22528	DES22533
DES25018	DES25023	DES25028	DES25033
DES27518	DES27523	DES27528	DES27533
DES30018	DES30023	DES30028	DES30033
DES32518	DES32523	DES32528	DES32533
DES35018	DES35023	DES35028	DES35033
DES40018	DES40023	DES40028	DES40033

DES20038	DES20043	DES20048
DES22538	DES22543	DES22548
DES25038	DES25043	DES25048
DES27538	DES27543	DES27548
DES30038	DES30043	DES30048
DES32538	DES32543	DES32548
DES35038	DES35043	DES35048
DES40038	DES40043	DES40048



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