



CERTIFICATE

EC Certificate No. **1434-MDD-524/2019**
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 DECO

Paclitaxel-Eluting PTCA Balloon Catheter

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: **123/2019**

Module **H**


Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-523/2019
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 DECO

Paclitaxel-Eluting PTCA Balloon Catheter

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: 123/2019

Module H


Anna Wyroba
Vice-President



ANNEX No 1 TO CERTIFICATE


VALID ONLY WITH CERTIFICATE

No **1434-MDD-523/2019**

MSM DECO– product table

DECO20010	DECO20015	DECO20020	DECO20025	DECO20030
DECO22510	DECO22515	DECO22520	DECO22525	DECO22530
DECO25010	DECO25015	DECO25020	DECO25025	DECO25030
DECO27510	DECO27515	DECO27520	DECO27525	DECO27530
DECO30010	DECO30015	DECO30020	DECO30025	DECO30030
DECO32510	DECO32515	DECO32520	DECO32525	DECO32530
DECO35010	DECO35015	DECO35020	DECO35025	DECO35030
DECO40010	DECO40015	DECO40020	DECO40025	DECO40030




Anna Wyroba
Vice-President