



CERTIFICATE

EC Certificate No. 1434-MDD-375/2021
EC Design-examination
Directive 93/42/EEC concerning medical devices

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

Kamal Encon Industries Limited
Plot No. 917, Sector-68, IMT, Faridabad 121001,
Haryana,
INDIA

related to the medical device, class III

Stenoflex Sirolimus Eluting Coronary Stent System /
Trackflex Sirolimus Eluting Coronary Stent System

The list of medical devices covered by this certificate is provided in the Annexes 1-2

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 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021



Issued under the Contract No. **MD-80/2020**
Application No: **139/2020**
Certificate bears the qualified signature.
Warsaw, 24/05/2021
Module H1

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.24
12:27:52 +02'00'



CERTIFICATE

EC Certificate No. 1434-MDD-376/2021
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:

Kamal Encon Industries Limited
Plot No. 917, Sector-68,IMT, Faridabad 121001,
Haryana,
INDIA

for the design, manufacture and final inspection of
medical devices, class III

Stenoflex Sirolimus Eluting Coronary Stent System /
Trackflex Sirolimus Eluting Coronary Stent System

The list of medical devices covered by this certificate is provided in the Annexes 1-2 to EC Design-examination Certificate No. 1434-MDD-375/2021

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 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021



Issued under the Contract No. **MD-80/2020**
Application No: **139/2020**
Certificate bears the qualified signature.
Warsaw, 24/05/2021
Module **H2/3/4/5**

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.24
12:30:09 +02'00'



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-375/2021

List of medical devices covered by the certificate:

Stenoflex Sirolimus Eluting Coronary Stent System

Diameter (mm)	Stent Length (mm)								
	8	9	12	13	15	16	18	20	23
2.00	SF20008	SF20009	SF20012	SF20013	SF20015	SF20016	SF20018	SF20020	SF20023
2.25	SF22508	SF22509	SF22512	SF22513	SF22515	SF22516	SF22518	SF22520	SF22523
2.50	SF25008	SF25009	SF25012	SF25013	SF25015	SF25016	SF25018	SF25020	SF25023
2.75	SF27508	SF27509	SF27512	SF27513	SF27515	SF27516	SF27518	SF27520	SF27523
3.00	SF30008	SF30009	SF30012	SF30013	SF30015	SF30016	SF30018	SF30020	SF30023
3.25	SF32508	SF32509	SF32512	SF32513	SF32515	SF32516	SF32518	SF32520	SF32523
3.50	SF35008	SF35009	SF35012	SF35013	SF35015	SF35016	SF35018	SF35020	SF35023
4.00	SF40008	SF40009	SF40012	SF40013	SF40015	SF40016	SF40018	SF40020	SF40023
4.50	SF45008	SF45009	SF45012	SF45013	SF45015	SF45016	SF45018	SF45020	SF45023

Diameter (mm)	Stent Length (mm)								
	24	28	32	33	36	38	40	43	47
2.00	SF20024	SF20028	SF20032	SF20033	SF20036	SF20038	SF20040	SF20043	SF20047
2.25	SF22524	SF22528	SF22532	SF22533	SF22536	SF22538	SF22540	SF22543	SF22547
2.50	SF25024	SF25028	SF25032	SF25033	SF25036	SF25038	SF25040	SF25043	SF25047
2.75	SF27524	SF27528	SF27532	SF27533	SF27536	SF27538	SF27540	SF27543	SF27547
3.00	SF30024	SF30028	SF30032	SF30033	SF30036	SF30038	SF30040	SF30043	SF30047
3.25	SF32524	SF32528	SF32532	SF32533	SF32536	SF32538	SF32540	SF32543	SF32547
3.50	SF35024	SF35028	SF35032	SF35033	SF35036	SF35038	SF35040	SF35043	SF35047
4.00	SF40024	SF40028	SF40032	SF40033	SF40036	SF40038	SF40040	SF40043	SF40047
4.50	SF45024	SF45028	SF45032	SF45033	SF45036	SF45038	SF45040	SF45043	SF45047



Issued under the Contract No. **MD-80/2020**
 Application No: **139/2020**
 Certificate bears the qualified signature.
 Warsaw, 24/05/2021

Anna
 Małgorzata
 Wyroba
 Vice-President

Elektronicznie
 podpisany przez Anna
 Małgorzata Wyroba
 Data: 2021.05.24
 12:28:44 +02'00'



ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-355/2021

List of medical devices covered by the certificate:

Trackflex Sirolimus Eluting Coronary Stent System

Stent Length (mm)									
Diameter (mm)	8	9	12	13	15	16	18	20	23
2.00	TF20008	TF20009	TF20012	TF20013	TF20015	TF20016	TF20018	TF20020	TF20023
2.25	TF22508	TF22509	TF22512	TF22513	TF22515	TF22516	TF22518	TF22520	TF22523
2.50	TF25008	TF25009	TF25012	TF25013	TF25015	TF25016	TF25018	TF25020	TF25023
2.75	TF27508	TF27509	TF27512	TF27513	TF27515	TF27516	TF27518	TF27520	TF27523
3.00	TF30008	TF30009	TF30012	TF30013	TF30015	TF30016	TF30018	TF30020	TF30023
3.25	TF32508	TF32509	TF32512	TF32513	TF32515	TF32516	TF32518	TF32520	TF32523
3.50	TF35008	TF35009	TF35012	TF35013	TF35015	TF35016	TF35018	TF35020	TF35023
4.00	TF40008	TF40009	TF40012	TF40013	TF40015	TF40016	TF40018	TF40020	TF40023
4.50	TF45008	TF45009	TF45012	TF45013	TF45015	TF45016	TF45018	TF45020	TF45023

Stent Length (mm)									
Diameter (mm)	24	28	32	33	36	38	40	43	47
2.00	TF20024	TF20028	TF20032	TF20033	TF20036	TF20038	TF20040	TF20043	TF20047
2.25	TF22524	TF22528	TF22532	TF22533	TF22536	TF22538	TF22540	TF22543	TF22547
2.50	TF25024	TF25028	TF25032	TF25033	TF25036	TF25038	TF25040	TF25043	TF25047
2.75	TF27524	TF27528	TF27532	TF27533	TF27536	TF27538	TF27540	TF27543	TF27547
3.00	TF30024	TF30028	TF30032	TF30033	TF30036	TF30038	TF30040	TF30043	TF30047
3.25	TF32524	TF32528	TF32532	TF32533	TF32536	TF32538	TF32540	TF32543	TF32547
3.50	TF35024	TF35028	TF35032	TF35033	TF35036	TF35038	TF35040	TF35043	TF35047
4.00	TF40024	TF40028	TF40032	TF40033	TF40036	TF40038	TF40040	TF40043	TF40047
4.50	TF45024	TF45028	TF45032	TF45033	TF45036	TF45038	TF45040	TF45043	TF45047



Issued under the Contract No. **MD-80/2020**
Application No: **139/2020**
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.24
12:29:25 +02'00'

Vice-President