



CERTIFICATE

EC Certificate No. 1434-MDD-355/2021
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

Everoshine Everolimus Eluting Coronary Stent System /
Trackmaster Everolimus 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-94/2020**
Application No: **230/2020**
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
12:24:43 +02'00'



CERTIFICATE

EC Certificate No. 1434-MDD-356/2021
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

Everoshine Everolimus Eluting Coronary Stent System /
Trackmaster Everolimus 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-355/2021

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-94/2020**
Application No: **230/2020**
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
12:26:57 +02'00'



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-355/2021

List of medical devices covered by the certificate:

Everoshine Everolimus Eluting Coronary Stent System

Diameter (mm)	Stent Length (mm)								
	8	9	12	13	15	16	18	20	23
2.00	ER20008	ER20009	ER20012	ER20013	ER20015	ER20016	ER20018	ER20020	ER20023
2.25	ER22508	ER22509	ER22512	ER22513	ER22515	ER22516	ER22518	ER22520	ER22523
2.50	ER25008	ER25009	ER25012	ER25013	ER25015	ER25016	ER25018	ER25020	ER25023
2.75	ER27508	ER27509	ER27512	ER27513	ER27515	ER27516	ER27518	ER27520	ER27523
3.00	ER30008	ER30009	ER30012	ER30013	ER30015	ER30016	ER30018	ER30020	ER30023
3.25	ER32508	ER32509	ER32512	ER32513	ER32515	ER32516	ER32518	ER32520	ER32523
3.50	ER35008	ER35009	ER35012	ER35013	ER35015	ER35016	ER35018	ER35020	ER35023
4.00	ER40008	ER40009	ER40012	ER40013	ER40015	ER40016	ER40018	ER40020	ER40023
4.50	ER45008	ER45009	ER45012	ER45013	ER45015	ER45016	ER45018	ER45020	ER45023

Diameter (mm)	Stent Length (mm)								
	24	28	32	33	36	38	40	43	47
2.00	ER20024	ER20028	ER20032	ER20033	ER20036	ER20038	ER20040	ER20043	ER20047
2.25	ER22524	ER22528	ER22532	ER22533	ER22536	ER22538	ER22540	ER22543	ER22547
2.50	ER25024	ER25028	ER25032	ER25033	ER25036	ER25038	ER25040	ER25043	ER25047
2.75	ER27524	ER27528	ER27532	ER27533	ER27536	ER27538	ER27540	ER27543	ER27547
3.00	ER30024	ER30028	ER30032	ER30033	ER30036	ER30038	ER30040	ER30043	ER30047
3.25	ER32524	ER32528	ER32532	ER32533	ER32536	ER32538	ER32540	ER32543	ER32547
3.50	ER35024	ER35028	ER35032	ER35033	ER35036	ER35038	ER35040	ER35043	ER35047
4.00	ER40024	ER40028	ER40032	ER40033	ER40036	ER40038	ER40040	ER40043	ER40047
4.50	ER45024	ER45028	ER45032	ER45033	ER45036	ER45038	ER45040	ER45043	ER45047



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Application No: **230/2020**
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Warsaw, 24/05/2021

Anna
Małgorzata
Wyroba

Elektronicznie podpisany
przez Anna Małgorzata
Wyroba
Data: 2021.05.24 12:25:26
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Vice-President



ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-355/2021

List of medical devices covered by the certificate:

Trackmaster Everolimus Eluting Coronary Stent System

Diameter (mm)	Stent Length (mm)								
	8	9	12	13	15	16	18	20	23
2.00	TR20008	TR20009	TR20012	TR20013	TR20015	TR20016	TR20018	TR20020	TR20023
2.25	TR22508	TR22509	TR22512	TR22513	TR22515	TR22516	TR22518	TR22520	TR22523
2.50	TR25008	TR25009	TR25012	TR25013	TR25015	TR25016	TR25018	TR25020	TR25023
2.75	TR27508	TR27509	TR27512	TR27513	TR27515	TR27516	TR27518	TR27520	TR27523
3.00	TR30008	TR30009	TR30012	TR30013	TR30015	TR30016	TR30018	TR30020	TR30023
3.25	TR32508	TR32509	TR32512	TR32513	TR32515	TR32516	TR32518	TR32520	TR32523
3.50	TR35008	TR35009	TR35012	TR35013	TR35015	TR35016	TR35018	TR35020	TR35023
4.00	TR40008	TR40009	TR40012	TR40013	TR40015	TR40016	TR40018	TR40020	TR40023
4.50	TR45008	TR45009	TR45012	TR45013	TR45015	TR45016	TR45018	TR45020	TR45023

Diameter (mm)	Stent Length (mm)								
	24	28	32	33	36	38	40	43	47
2.00	TR20024	TR20028	TR20032	TR20033	TR20036	TR20038	TR20040	TR20043	TR20047
2.25	TR22524	TR22528	TR22532	TR22533	TR22536	TR22538	TR22540	TR22543	TR22547
2.50	TR25024	TR25028	TR25032	TR25033	TR25036	TR25038	TR25040	TR25043	TR25047
2.75	TR27524	TR27528	TR27532	TR27533	TR27536	TR27538	TR27540	TR27543	TR27547
3.00	TR30024	TR30028	TR30032	TR30033	TR30036	TR30038	TR30040	TR30043	TR30047
3.25	TR32524	TR32528	TR32532	TR32533	TR32536	TR32538	TR32540	TR32543	TR32547
3.50	TR35024	TR35028	TR35032	TR35033	TR35036	TR35038	TR35040	TR35043	TR35047
4.00	TR40024	TR40028	TR40032	TR40033	TR40036	TR40038	TR40040	TR40043	TR40047
4.50	TR45024	TR45028	TR45032	TR45033	TR45036	TR45038	TR45040	TR45043	TR45047



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Warsaw, 24/05/2021

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Małgorzata Wyroba
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Vice-President