

EC Design Examination Certificate



according the directive 93/42/EEC,
Annex II (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

B. Braun Melsungen AG

Carl-Braun-Straße 1, 34212 Melsungen, Germany

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC Annex II.4 as documented in the report mentioned in the annex.

Product: **Coroflex ISAR NEO
Sirolimus Eluting Coronary Stent System**

This certificate is valid from 2020-11-19 to 2024-05-26

Registration No.: 51342-23-G1



Notified Body ID-number: 0124

rt; 2020-11-19



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Annex to the EC Design Examination Certificate No. 51342-23-G1

Revision status: 0

Valid from 2020-11-19 to 2024-05-26

Report number: 51342-P7-04

Product: Coroflex ISAR NEO Sirolimus Eluting Coronary Stent System

Intended use:

The Coroflex ISAR NEO Sirolimus Eluting Coronary Stent System is intended for improving intraluminal diameter in coronary vessels and to reduce the possible event of restenosis.

Technical data:

Length [mm]	9-38			
Diameter [mm]	2.0 - 4.0			
Stent coating drug	Sirolimus			
Article code	5028910	5028917	5028924	5028931
	5028911	5028918	5028925	5028932
	5028912	5028919	5028926	5028933
	5028913	5028920	5028927	5028934
	5028914	5028921	5028928	5028935
	5028915	5028922	5028929	5028936
	5028916	5028923	5028930	5028937
	5028938	5028945	5028952	5028959
	5028939	5028946	5028953	5028960
	5028940	5028947	5028954	5028961
	5028941	5028948	5028955	5028962
	5028942	5028949	5028956	5028963
	5028943	5028950	5028957	5028964
	5028944	5028951	5028958	5028965

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