AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE_Design Examination
I.3. Certificatul CE	Certificat CE_Full Quality
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		guidion								
DM000195389	EXTENSIE FLEXIBILĂ DE GHIDARE	Guidion	6F ID ≥0.070″	G60F25150	Olanda	IMDS OPERATIONS B.V.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000195390	EXTENSIE FLEXIBILĂ DE GHIDARE	Guidion	7F ID ≥0.078″	G70F25150	Olanda	IMDS OPERATIONS B.V.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000195391	EXTENSIE FLEXIBILĂ DE GHIDARE	Guidion	8F ID ≥0.088″	G80F25150	Olanda	IMDS OPERATIONS B.V.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000195388	EXTENSIE FLEXIBILĂ DE GHIDARE	Guidion	5F ID ≥0.056″	G50F25150	Olanda	IMDS OPERATIONS B.V.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	

Содержит([NameMake], 'guidion')

Очистить

IMDS
INTERVENTIONAL MEDICAL DEVICE SOLUTIONS

EC DECLARATION OF CONFORMITY

to

MEDICAL DEVICES DIRECTIVE 93/42/EEC

Manufacturer:	IMDS Operations B.V. Ceintuurbaan Noord 150 9301 NZ Roden The Netherlands	Telephone: Fax:	+31 (0)50 8200 230 +31 (0)50 8200 231

Product: Guidion (Guidion Rapid Exchange Guide Extension)

Catalog numbers: Guidion: G50F25150; G60F25150; G70F25150; G80F25150

Conformity route: Annex II (incl. section 4) in accordance with MDD93/42/EEC of June 14, 1993.

Classification: Class III in accordance with MDD93/42/EEC of June 14, 1993, Annex IX, section III, rule 6.

GMDN: 17846; Catheter, Intravascular, Guiding.

IMDS Operations B.V. hereby declares that the Guidion Rapid Exchange Guide Extension product is in conformance to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and amendments. All supporting documentation is retained under the premises of the manufacturer.

A table of relevant standards for which documented evidence of compliance can be provided is stated in the table below.

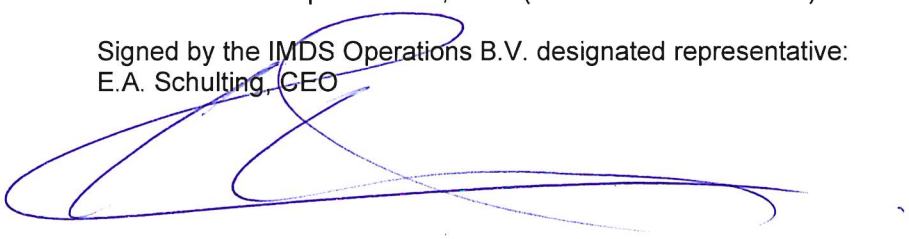
Table of relevant standards		
NEN EN ISO 80369-7: 2017 en	NEN EN ISO 11607-1: 2017 en / Cor: 2017-11	NEN EN 556-1: 2001 en / C1: 2006
NEN EN ISO 80369-20: 2015 en	NEN EN ISO 11607-2: 2017 en	NEN EN 1041: 2008 en + A1: 2013
NEN EN ISO 10555-1: 2013 en / A1: 2018	NEN EN ISO 13485: 2016 en	NEN EN ISO 11137-1: 2015 en
NEN EN ISO 10993-1: 2009 -10 en / C1: 2010	BS EN ISO 14971: 2012	NEN EN ISO 11137-2: 2015 en
NEN EN ISO 10993-4: 2017-10 en	NEN EN ISO 14644-1: 2016 en	NEN EN ISO 11737-1: 2018 en
NEN EN ISO 10993-5: 2009 en	NEN EN ISO 14644-2: 2016 en	NEN EN ISO 11737-2: 2009 en
NEN EN ISO 10993-10: 2013 en	NEN EN ISO 15223-1:2016 en / Cor: 2017-04	NEN EN IEC 62366-1: 2015 en / C11: 2016
NEN EN ISO 10993-11: 2018 en	NEN EN ISO 2233: 2001 en	NEN-EN-ISO 14155:2011 en / C1: 2011
NEN EN ISO 10993-12: 2012 en		

IMDS Operations B.V. declares that the Guidion product has been registered as a Class III medical device, under registration number 0344/2238714CE01/2238714DE05, at DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem, The Netherlands.

IMDS Operations B.V. confirms that no medicinal products/drugs or material of animal origin are incorporated in the Guidion product.

Effective date: September 10, 2019 (Lot break: R190515002)

Signed by the IMDS Operations B.V. designated representative:
E.A. Schulting, CEO



Signed at: Roden, The Netherlands, Date: September 16, 2019

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2238714DE05

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

For the product

Guidion Rapid Exchange Guide Extension

Documents, that form the basis of this certificate:

Certification Notice 2238714CN, initially dated 10 September 2019
CE Marking of Conformity 2238714CE01
Addendum, initially dated 20 December 2019

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 24 May 2024
Issued for the first time: 10 September 2019
Revised: 20 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2238714DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Guidion Rapid Exchange Guide Extension

Issued to:

IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

This certificate covers the following product(s):

Product codes
G50F25150
G60F25150
G70F25150
G80F25150

Initial date: 20 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

EC CERTIFICATE

Number: 2238714CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:
IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

For the product category(ies)

Catheters and dilatation catheters for cardiovascular use

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2238714CN, initially dated 10 September 2019
Addendum, initially dated 10 September 2019

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 10 September 2019
Reissued: 30 March 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2238714CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Catheters and dilatation catheters for cardiovascular use

Issued to:

IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

This certificate covers the following product(s):

- Blimp Balloon Catheter
- NHancer Guide Wire Support Catheter with Hydrophilic Coating
- TrapIT Trapping Balloon Catheter
- ReCross OTW Dual Lumen Guide Wire Support Catheter
- Guidion Rapid Exchange Guide Extension

Initial date: 10 September 2019
Revision date: 20 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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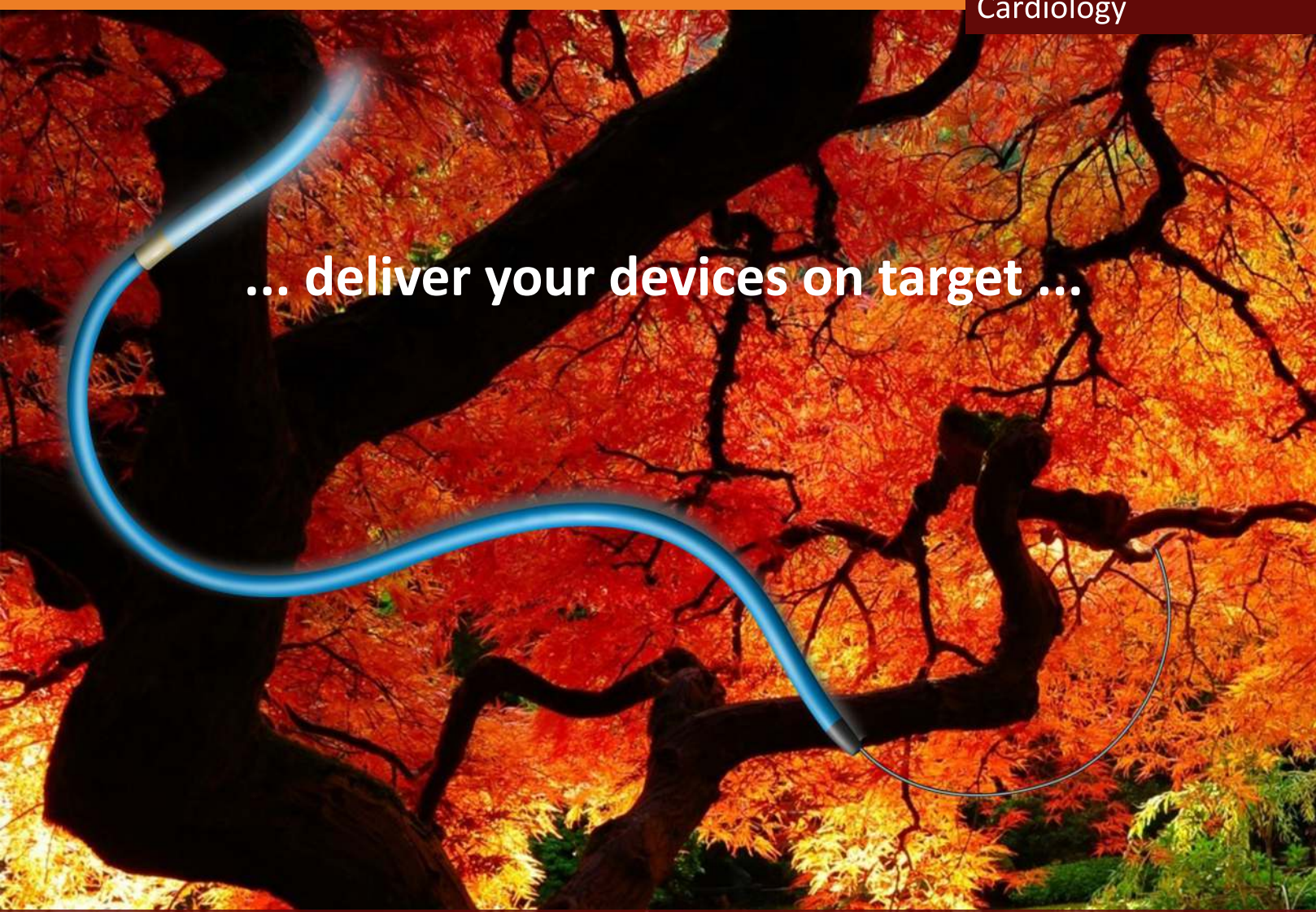
IMDS
INTERVENTIONAL MEDICAL DEVICE SOLUTIONS
... increasing quality of life ...

GUIDION HYDRO

RAPID EXCHANGE GUIDE EXTENSION

Cardiology



Procedural success rates

Deep-seating

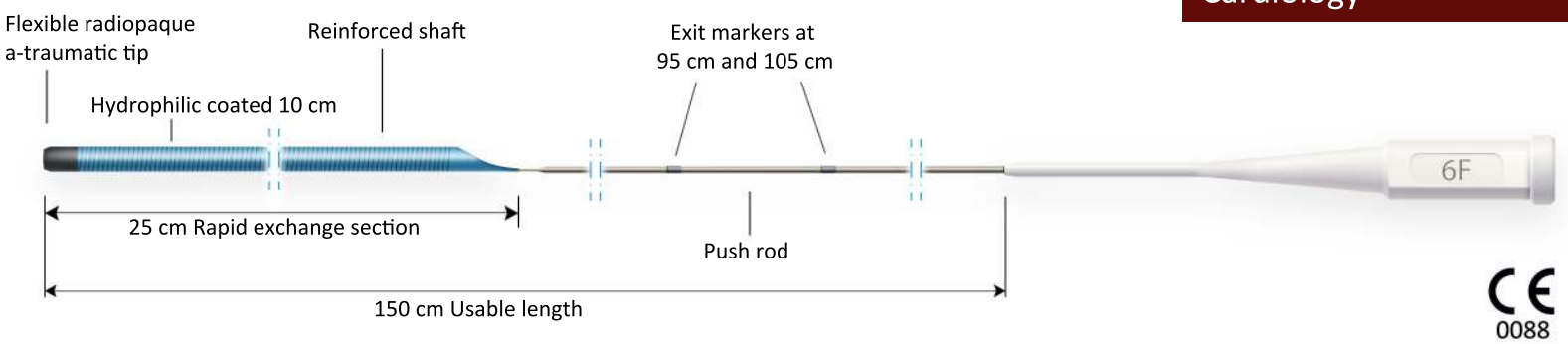
Flexible Guide Extension

IMDS
INTERVENTIONAL MEDICAL DEVICE SOLUTIONS
... increasing quality of life ...

GUIDION HYDRO

RAPID EXCHANGE GUIDE EXTENSION

Cardiology



CE 0088

Radiopaque soft tip marker

Rapid exchange transition

Outstanding crossability

Model	Required guide catheter ID	Guidion ID	Rapid exchange length	Usable length	Hydrophilic coating length
G50F25150	5F ID ≥0.056" (1.42 mm)	0.041" (1.04 mm)	25 cm	150 cm	10 cm
G60F25150	6F ID ≥0.070" (1.78 mm)	0.056" (1.42 mm)	25 cm	150 cm	10 cm
G70F25150	7F ID ≥0.078" (1.98 mm)	0.062" (1.57 mm)	25 cm	150 cm	10 cm
G80F25150	8F ID ≥0.088" (2.24 mm)	0.071" (1.80 mm)	25 cm	150 cm	10 cm

Guidion™ Flexible Guide Extension

- Significant improvement in backup support
- Selective contrast injections
- Guidion Hydro is provided with a low friction hydrophilic coating on the distal part of the extension to support smooth vessel crossing

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.
Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.
Guidion™ is a trademark of IMDS.

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For more information
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ITM130156 R6.0