

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2161507DE03

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

Manufacturer:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.
İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

For the product

Cardiovascular Angiographic Catheters

Documents, that form the basis of this certificate:

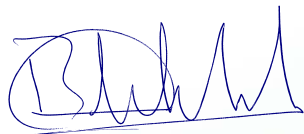
Certification Notice 2161507CN, initially dated 9 April 2013
CE Marking of Conformity 2161507CE02
Addendum, initially dated 23 May 2013

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: 1 June 2023
Issued for the first time: 23 May 2013
Revised: 5 May 2021
Reissued: 14 June 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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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: 2161507DE03

1/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

Cardiovascular Angiographic Catheters

Issued to:

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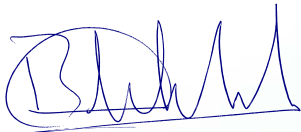
This certificate covers the following product(s):

Alvision™ Interventional Cardiology Diagnostic Catheter:

ALVISION INTERVENTIONAL CARDIOLOGY DC 5 PACK CONFIGARATION

Current Ref. Code	Size	Product Definition	Curve Type and Length
501110019601	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 – 100 cm
501110019602	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 – 100 cm
501110019603	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 – 100 cm
501110019604	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP – 100 cm
501110019605	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 – 100 cm
501110019606	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 – 100 cm
501110019607	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 – 100 cm
501110019608	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 – 100 cm
501110019609	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 – 100 cm
501110019610	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 – 100 cm
501110019611	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 – 100 cm
501110019612	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 – 100 cm
501110019613	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 – 100 cm
501110019614	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I – 100 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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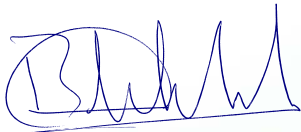
Cardiovascular Angiographic Catheters

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501110019615	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II – 100 cm
501110019631	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110019632	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110019633	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm
501110019634	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP – 100 cm
501110019635	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP – 100 cm
501110019636	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP – 100 cm
501110019637	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 110 cm
501110019638	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 110 cm
501110019639	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 110 cm
501110019640	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110019641	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ALVISION ATEŞAL 3.5 - 100 cm
501110019616	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110019617	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110019618	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110019619	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110019620	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm
501110019621	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT- 100 cm
501110019622	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm
501110019623	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110019624	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm

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B.T.M. Holtus
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J.A. van Vugt
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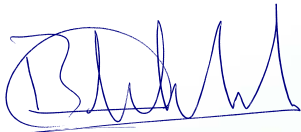
Cardiovascular Angiographic Catheters

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501110019625	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 - 100 cm
501110019626	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 - 100 cm
501110019627	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 - 100 cm
501110019628	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110019629	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110019630	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110019652	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm
501110019701	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110019702	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110019703	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP - 100 cm
501110019704	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm
501110019705	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110019706	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110019707	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110019708	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110019709	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110019710	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110019642	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 -100cm
501110019643	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK -100cm
501110019644	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100cm
501110019647	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100cm

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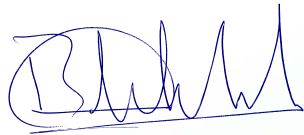
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501110019648	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP -100cm
501110019651	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100cm
501110019718	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110019719	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110019720	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm
501110019721	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT - 100 cm
501110019722	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm
501110019723	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110019724	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm
501110019725	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 - 100 cm
501110019726	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 - 100 cm
501110019727	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 - 100 cm
501110019728	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110019729	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110019730	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110019731	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110019732	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110019733	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm
501110019734	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm
501110019735	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm
501110019736	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm

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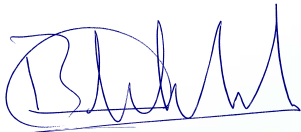
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501110019737	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 110 cm
501110019738	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 110 cm
501110019711	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110019712	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110019714	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm
501110019715	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110019716	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110019717	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110019802	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110019803	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm
501110019804	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP - 100 cm
501110019805	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110019806	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110019807	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110019808	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110019809	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110019810	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110019811	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110019812	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110019813	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm
501110019814	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm

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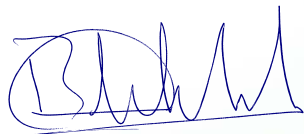
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501110019815	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110019816	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110019817	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110019818	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110019740	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm
501110019741	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110019742	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm
501110019743	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm
501110019739	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 -110 cm
501110019744	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT-100 cm
501110019747	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4-100 cm
501110019748	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm
501110019751	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm
501110019752	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT-100 cm
501110019801	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110019819	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110019820	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm
501110019821	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT - 100 cm
501110019822	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm
501110019823	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110019824	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm

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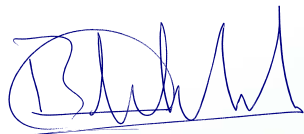
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501110019826	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1- 100 cm
501110019827	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2- 100 cm
501110019828	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110019829	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110019830	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110019831	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -80 cm
501110019832	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -80 cm
501110019833	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -80 cm
501110019834	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm
501110019835	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP -100 cm
501110019905	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 -100 cm
501110019906	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -100 cm
501110019907	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -100 cm
501110019836	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP -100 cm -100 cm
501110019837	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL STRAIGHT 110 cm
501110019838	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 145 - 110 cm
501110019839	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 155 - 110 cm
501110019840	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5-100 cm
501110019841	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0-100 cm
501110019842	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5-100 cm

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EC DESIGN-EXAMINATION MEDICAL DEVICES

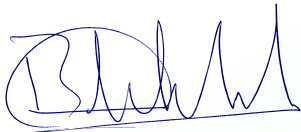
Cardiovascular Angiographic Catheters

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Çatalca-İstanbul
TÜRKİYE

501110019843	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK-100 cm
501110019844	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT-100 cm
501110019847	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4-100 cm
501110019848	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm
501110019851	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm
501110019852	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT-100 cm
501110019901	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 -100 cm
501110019902	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 -100 cm
501110019903	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -100 cm
501110019904	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP -100 cm
501110019922	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT – 100 cm
501110019923	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY – 100 cm
501110019924	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 – 100 cm
501110019925	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 -100 cm
501110019926	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 -100 cm
501110019927	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 -100 cm
501110019928	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -100 cm
501110019929	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -100 cm
501110019930	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -100 cm
501110019931	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -80 cm
501110019908	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 -100 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

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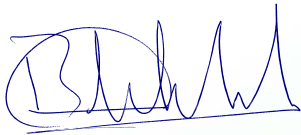
Cardiovascular Angiographic Catheters

Issued to:

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Çatalca-İstanbul
TÜRKİYE

501110019909	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 -100 cm
501110019910	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -100 cm
501110019911	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 -100 cm
501110019912	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -100 cm
501110019913	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -100 cm
501110019914	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I -100 cm
501110019915	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II -100 cm
501110019932	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -80 cm
501110019933	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -80 cm
501110019934	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP -100 cm
501110019935	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP -100 cm
501110019936	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP -100 cm
501110019937	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL STRAIGHT -110 cm
501110019938	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 145 -110 cm
501110019947	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100 cm
501110019916	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110019917	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I -100 cm
501110019918	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II -100 cm
501110019919	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III -100 cm
501110019920	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B -100 cm
501110019921	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT -100cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

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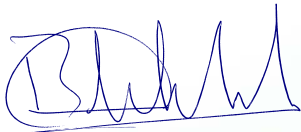
Cardiovascular Angiographic Catheters

Issued to:

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İstanbul Trakya Serbest Bölgesi,
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Çatalca-İstanbul
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501110019948	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm
501110019951	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm
501110019939	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155- 110 cm
501110019940	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 -100 cm
501110019941	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5-100 cm
501110019942	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5-100 cm
501110019943	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK-100 cm
501110019944	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT -100 cm
501110019952	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT -100 cm
501110019501	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm
501110019502	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm
501110019503	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm
501110019504	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm
501110019505	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm
501110019506	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -125 cm
501110019507	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm
501110019508	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm
501110019509	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm
501110019526	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm
501110019527	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm
501110019510	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

11/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

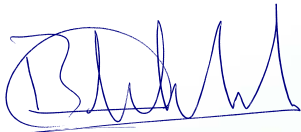
Cardiovascular Angiographic Catheters

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110019511	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm
501110019512	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -125cm
501110019513	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm
501110019514	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm
501110019515	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm
501110019516	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm
501110019517	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm
501110019518	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0-125 cm
501110019519	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145°-125 cm
501110019520	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155°-125 cm
501110019521	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145°-125 cm
501110019522	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155°-125 cm
501110019523	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145°-125 cm
501110019524	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155°-125 cm
501110019525	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm

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B.T.M. Holtus
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J.A. van Vugt
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Cardiovascular Angiographic Catheters

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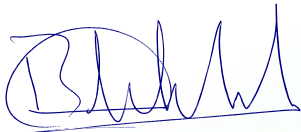
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Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

ALVISION INTERVENTIONAL CARDIOLOGY DC 10 PACK CONFIGARATION

Current Ref.

Code	Size	Product Definition	Curve Type and Length
501110188401	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110188402	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110188403	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm
501110188404	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm
501110188405	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110188406	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110188407	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110188408	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110188409	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110188410	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110188411	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110188412	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110188413	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm
501110188414	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm
501110188415	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110188416	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110188417	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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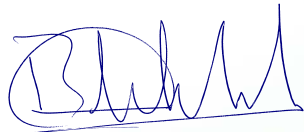
Cardiovascular Angiographic Catheters

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Çatalca-İstanbul
TÜRKİYE

501110188432	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110188433	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110188434	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm
501110188435	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm
501110188436	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm
501110188418	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110188419	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110188420	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm
501110188421	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT - 100 cm
501110188422	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm
501110188423	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110188424	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm
501110188425	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm
501110188426	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm
501110188427	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm
501110188428	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110188429	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110188430	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110188431	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110188432	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110188433	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm

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B.T.M. Holtus
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J.A. van Vugt
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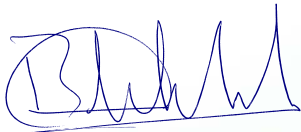
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Çatalca-İstanbul
TÜRKİYE

501110188431	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110188520	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B -100 cm
501110188521	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT- 100 cm
501110188522	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm
501110188523	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110188524	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm
501110188437	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm
501110188438	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm
501110188439	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm
501110188440	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm
501110188441	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110188442	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm
501110188443	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm
501110188444	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm
501110188447	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm
501110188448	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm
501110188451	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm
501110188452	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm
501110188501	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110188502	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110188503	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION MEDICAL DEVICES

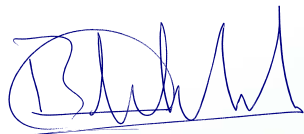
Cardiovascular Angiographic Catheters

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110188504	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm
501110188505	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110188506	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110188507	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110188508	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110188509	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110188510	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110188511	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110188512	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110188513	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm
501110188514	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm
501110188525	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm
501110188526	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm
501110188527	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm
501110188528	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110188529	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110188530	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110188531	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110188532	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110188533	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm
501110188534	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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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: 2161507DE03

16/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

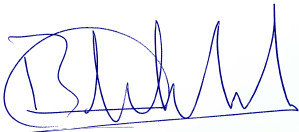
Cardiovascular Angiographic Catheters

Issued to:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.
İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110188535	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm
501110188536	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm
501110188537	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm
501110188538	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm
501110188539	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm
501110188540	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm
501110188541	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110188542	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm
501110188543	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm
501110188544	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm
501110188547	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100 cm
501110188548	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm
501110188551	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm
501110188552	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm
501110188601	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110188602	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110188515	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110188516	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110188517	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110188518	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110188519	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

17/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

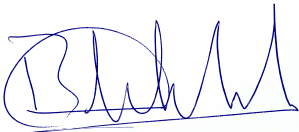
Cardiovascular Angiographic Catheters

Issued to:

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İstanbul Trakya Serbest Bölgesi,
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Çatalca-İstanbul
TÜRKİYE

501110188608	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110188609	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110188610	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110188611	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110188612	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110188613	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm
501110188614	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm
501110188615	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110188616	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110188617	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110188618	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110188619	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110188620	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED - 100 cm
501110188621	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT - 100 cm
501110188622	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm
501110188623	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110188624	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm
501110188625	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm
501110188626	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm
501110188603	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm
501110188604	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

18/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

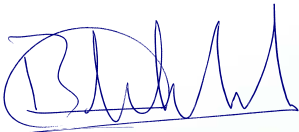
Cardiovascular Angiographic Catheters

Issued to:

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
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TÜRKİYE

501110188605	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110188606	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110188607	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110188644	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm
501110188647	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm
501110188648	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm
501110188651	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm
501110188652	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm
501110188701	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm
501110188702	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm
501110188703	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm
501110188704	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm
501110188705	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm
501110188706	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm
501110188707	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm
501110188708	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm
501110188709	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm
501110188710	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm
501110188711	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm
501110188712	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm
501110188713	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

19/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

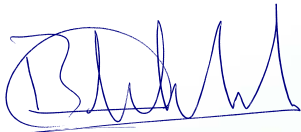
Cardiovascular Angiographic Catheters

Issued to:

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110188714	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm
501110188627	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm
501110188628	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110188629	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm
501110188630	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110188631	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110188632	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110188633	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm
501110188634	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm
501110188635	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm
501110188636	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm
501110188637	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm
501110188638	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm
501110188639	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm
501110188640	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm
501110188641	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110188642	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm
501110188643	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm
501110188732	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm
501110188733	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm
501110188734	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

20/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

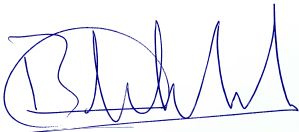
Cardiovascular Angiographic Catheters

Issued to:

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110188735	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm
501110188736	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm
501110188737	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm
501110188738	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm
501110188739	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm
501110188740	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm
501110188715	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm
501110188716	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm
501110188717	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm
501110188718	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm
501110188719	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm
501110188720	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm
501110188721	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT - 100 cm
501110188722	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm
501110188723	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm
501110188724	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm
501110188725	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm
501110188726	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm
501110188727	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm
501110188728	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm
501110188729	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507DE03

21/21

EC DESIGN-EXAMINATION MEDICAL DEVICES

Cardiovascular Angiographic Catheters

Issued to:

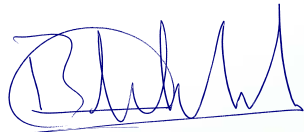
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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540
Çatalca-İstanbul
TÜRKİYE

501110188730	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm
501110188731	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm
501110188741	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm
501110188742	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm
501110188743	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm
501110188744	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm
501110188747	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm
501110188748	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm
501110188751	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm
501110188752	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm

Initial date: 23 May 2013

Revision date: 25 May 2021

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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EC CERTIFICATE

Number: 2161507CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Alvimedica Tıbbi Ürünler San.ve Dış Tic. A.Ş.

İstanbul Trakya Serbest Bölgesi,

Ferhatpaşa SB Mahallesi

Atatürk Bulvarı No:16 34540

Çatalca-İstanbul

TÜRKİYE

For the product category(ies)

Medical devices for cardiovascular interventions applications

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:

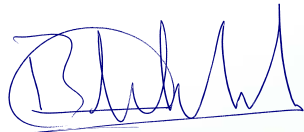
Certification Notice 2161507CN, initially dated 9 April 2013

Addendum, initially dated 23 May 2013

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: 1 June 2023
Issued for the first time: 23 May 2013
Revised: 25 May 2021
Reissued: 14 June 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2161507CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical devices for cardiovascular interventions applications

Issued to:

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İstanbul Trakya Serbest Bölgesi,
Ferhatpaşa SB Mahallesi
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TÜRKİYE

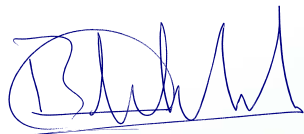
This certificate covers the following product(s):

- PTCA Balloon Dilatation Catheters
 - Invader™ CTO Balloon Dilatation Catheter;
 - Invader™ PTCA Balloon Dilatation Catheter;
- Bare Metal Stent Systems for Coronary Use
 - Ephesos™ II Bare Metal Stent;
 - Commander™ CoCr Bare Metal Stent;
 - Constant™ Bare Metal Stent;
- Cardiovascular Angiographic Catheters
 - Alvision™ Interventional Cardiology Diagnostic Catheter
- Cardiovascular Guiding Catheters
 - Alviguide™ Blue+ Interventional Cardiology Guiding Catheter

Initial date: 23 May 2013

Revision date: 25 May 2021

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