



EC Declaration of Conformity for Medical Devices

We, the undersigned Alvimedica Istanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi Atatürk Bulvarı No:16 34540 Çatalca/Istanbul Türkiye

EMDN code is C010401020101

hereby declare under our sole responsibility that the products listed here below

Basic UDI-DI	Product	Product Code	Model Code	Class	EC Product Certificate	Issue Date
086991955InvaderPTCAVA	Invader™ PTCA Balloon Dilatation Catheter	512110021610	INVADER PTCA BALLOON DILATATION CATHETER 1.25X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021611	INVADER PTCA BALLOON DILATATION CATHETER 1.25X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021612	INVADER PTCA BALLOON DILATATION CATHETER 1.25X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021613	INVADER PTCA BALLOON DILATATION CATHETER 1.25X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021614	INVADER PTCA BALLOON DILATATION CATHETER 1.25X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021615	INVADER PTCA BALLOON DILATATION CATHETER 1.50X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021616	INVADER PTCA BALLOON DILATATION CATHETER 1.50X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021617	INVADER PTCA BALLOON DILATATION CATHETER 1.50X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021618	INVADER PTCA BALLOON DILATATION CATHETER 1.50X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021619	INVADER PTCA BALLOON DILATATION CATHETER 2.00X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021619	INVADER PTCA BALLOON DILATATION CATHETER 2.00X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021503	INVADER PTCA BALLOON DILATATION CATHETER 2.00X12	Class III	NA	NA

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086991955InvaderPTCAVA	Invader™ PTCA Balloon Dilatation Catheter	512110021504	INVADER PTCA BALLOON DILATATION CATHETER 2.00X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021506	INVADER PTCA BALLOON DILATATION CATHETER 2.00X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021508	INVADER PTCA BALLOON DILATATION CATHETER 2.00X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021620	INVADER PTCA BALLOON DILATATION CATHETER 2.25X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021621	INVADER PTCA BALLOON DILATATION CATHETER 2.25X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021622	INVADER PTCA BALLOON DILATATION CATHETER 2.25X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021623	INVADER PTCA BALLOON DILATATION CATHETER 2.25X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021624	INVADER PTCA BALLOON DILATATION CATHETER 2.25X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021625	INVADER PTCA BALLOON DILATATION CATHETER 2.25X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021626	INVADER PTCA BALLOON DILATATION CATHETER 2.50X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021627	INVADER PTCA BALLOON DILATATION CATHETER 2.50X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021509	INVADER PTCA BALLOON DILATATION CATHETER 2.50X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021510	INVADER PTCA BALLOON DILATATION CATHETER 2.50X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021512	INVADER PTCA BALLOON DILATATION CATHETER 2.50X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021514	INVADER PTCA BALLOON DILATATION CATHETER 2.50X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021516	INVADER PTCA BALLOON DILATATION CATHETER 2.50X30	Class III	NA	NA
Invader™ PTCA Balloon Dilatation Catheter	512110021517	INVADER PTCA BALLOON DILATATION CATHETER 2.50X34	Class III	NA	NA	
Invader™ PTCA Balloon Dilatation Catheter	512110021628	INVADER PTCA BALLOON DILATATION CATHETER 2.75X6	Class III	NA	NA	

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086991955InvaderPTCAVA	Invader™ PTCA Balloon Dilatation Catheter	512110021629	INVADER PTCA BALLOON DILATATION CATHETER 2.75X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021551	INVADER PTCA BALLOON DILATATION CATHETER 2.75X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021552	INVADER PTCA BALLOON DILATATION CATHETER 2.75X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021554	INVADER PTCA BALLOON DILATATION CATHETER 2.75X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021556	INVADER PTCA BALLOON DILATATION CATHETER 2.75X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021558	INVADER PTCA BALLOON DILATATION CATHETER 2.75X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021559	INVADER PTCA BALLOON DILATATION CATHETER 2.75X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021630	INVADER PTCA BALLOON DILATATION CATHETER 3.00X6	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021631	INVADER PTCA BALLOON DILATATION CATHETER 3.00X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021518	INVADER PTCA BALLOON DILATATION CATHETER 3.00X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021519	INVADER PTCA BALLOON DILATATION CATHETER 3.00X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021521	INVADER PTCA BALLOON DILATATION CATHETER 3.00X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021523	INVADER PTCA BALLOON DILATATION CATHETER 3.00X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021525	INVADER PTCA BALLOON DILATATION CATHETER 3.00X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021526	INVADER PTCA BALLOON DILATATION CATHETER 3.00X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021632	INVADER PTCA BALLOON DILATATION CATHETER 3.25X10	Class III	NA	NA
Invader™ PTCA Balloon Dilatation Catheter	512110021633	INVADER PTCA BALLOON DILATATION CATHETER 3.25X12	Class III	NA	NA	
Invader™ PTCA Balloon Dilatation Catheter	512110021634	INVADER PTCA BALLOON DILATATION CATHETER 3.25X15	Class III	NA	NA	

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Basic UDI-DI	Product	Product Code	Model Code	Class	EC Product Certificate	Issue Date
086991955InvaderPTCAVA	Invader™ PTCA Balloon Dilatation Catheter	512110021635	INVADER PTCA BALLOON DILATATION CATHETER 3.25X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021636	INVADER PTCA BALLOON DILATATION CATHETER 3.25X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021637	INVADER PTCA BALLOON DILATATION CATHETER 3.25X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021638	INVADER PTCA BALLOON DILATATION CATHETER 3.25X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021639	INVADER PTCA BALLOON DILATATION CATHETER 3.50X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021527	INVADER PTCA BALLOON DILATATION CATHETER 3.50X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021528	INVADER PTCA BALLOON DILATATION CATHETER 3.50X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021530	INVADER PTCA BALLOON DILATATION CATHETER 3.50X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021532	INVADER PTCA BALLOON DILATATION CATHETER 3.50X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021534	INVADER PTCA BALLOON DILATATION CATHETER 3.50X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021535	INVADER PTCA BALLOON DILATATION CATHETER 3.50X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021640	INVADER PTCA BALLOON DILATATION CATHETER 3.75X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021641	INVADER PTCA BALLOON DILATATION CATHETER 3.75X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021642	INVADER PTCA BALLOON DILATATION CATHETER 3.75X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021643	INVADER PTCA BALLOON DILATATION CATHETER 3.75X20	Class III	NA	NA
Invader™ PTCA Balloon Dilatation Catheter	512110021644	INVADER PTCA BALLOON DILATATION CATHETER 3.75X25	Class III	NA	NA	
Invader™ PTCA Balloon Dilatation Catheter	512110021645	INVADER PTCA BALLOON DILATATION CATHETER 3.75X30	Class III	NA	NA	
Invader™ PTCA Balloon Dilatation Catheter	512110021646	INVADER PTCA BALLOON DILATATION CATHETER 3.75X34	Class III	NA	NA	

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086991955InvaderPTCAVA	Invader™ PTCA Balloon Dilatation Catheter	512110021647	INVADER PTCA BALLOON DILATATION CATHETER 4.00X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021536	INVADER PTCA BALLOON DILATATION CATHETER 4.00X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021537	INVADER PTCA BALLOON DILATATION CATHETER 4.00X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021539	INVADER PTCA BALLOON DILATATION CATHETER 4.00X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021541	INVADER PTCA BALLOON DILATATION CATHETER 4.00X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021543	INVADER PTCA BALLOON DILATATION CATHETER 4.00X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021544	INVADER PTCA BALLOON DILATATION CATHETER 4.00X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021648	DILATATION CATHETER 4.50X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021546	DILATATION CATHETER 4.50X12	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021547	DILATATION CATHETER 4.50X15	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021549	INVADER PTCA BALLOON DILATATION CATHETER 4.50X20	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021649	INVADER PTCA BALLOON DILATATION CATHETER 4.50X25	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021650	INVADER PTCA BALLOON DILATATION CATHETER 4.50X30	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021651	INVADER PTCA BALLOON DILATATION CATHETER 4.50X34	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021652	INVADER PTCA BALLOON DILATATION CATHETER 5.00X10	Class III	NA	NA
	Invader™ PTCA Balloon Dilatation Catheter	512110021653	INVADER PTCA BALLOON DILATATION CATHETER 5.00X12	Class III	NA	NA
Invader™ PTCA Balloon Dilatation Catheter	512110021654	DILATATION CATHETER 5.00X15	Class III	NA	NA	
Invader™ PTCA Balloon Dilatation Catheter	512110021655	INVADER PTCA BALLOON DILATATION CATHETER 5.00X20	Class III	NA	NA	

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which CE certificates issued by ICM, as Notified Body n° 0425, are conforming according to Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation of Regulation 2017/745 and subsequent updating concerning medical devices.

It is also guaranteed that the indicated products meet all applicable provisions of the named Regulation.


This declaration is issued based on the
EU Quality Management System Certificate n°: 0425-MDR-006772-00
EU Technical Documentation Assessment Certificate n°: 0425-MDR-006773-00

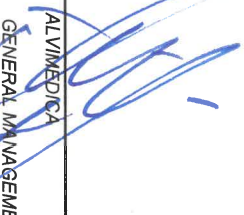
This EC DECLARATION OF CONFORMITY is valid for the medical devices manufactured under Alvimedica responsibility.

This declaration expires on: 03/07/2028

Catalca,


ALVIMEDICA
MANAGEMENT REPRESENTATIVE
04.07.2023


04.07.2023


ALVIMEDICA
GENERAL MANAGEMENT