DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42 EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Manufacturer:	SHENZHEN ANTMED CO.,LTD Add: 18 Jinhui Ave., Pingshan New District, Shenzhen, 518122, China
MEDICAL DEVICE:	Contrast Media Injectors
SPECIFICATION:	ImaStar CDP, ImaStar CSP, ImaStar CDC, ImaStar MDP, ImaStar ASP
CLASSIFICATION:	CLASS IIb, RULE 10
CONFORMITY ASSESSMENT ROUTE:	ANNEX II excluding (4)

We, the manufacturer, here with declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;

Including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC.

All supporting documentation is retained at the premises of the manufacturer.

(WE，AS MANFACTURER，ARE EXCLUSIVELY RESPONSIPLE FOR THE DECLARATION OF CONFORMITY.)

NOTIFIED BODY:	TÜV SÜD Product service GmbH Ridlerstr 65, 80339 München, Germany
IDENTION NUMBER:	CE 0123
(EC)CERTIFICATE(S):	G1 004593 0002 Rev.01
VALID UNTIL:	2024-05-26
EC REP European Representative:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany.

START of CE-MARKING:	None
PLACE,DATE OF DECLARATION:	SHENZHEN, 2020-03-03

SIGNATURE:

NAME: MR. FENG GAO

POSITION: MANAGEMENT REPRESENTATIVE

Digitally signed by Matei Vasile
Date: 2023.02.08 21:41:21 EET
Reason: MoldSign Signature
Location: Moldova