



# EC Declaration of Conformity



according to the Medical Devices Regulations (EU)2017/745

<b>Manufacturer:</b>	Shenzhen Boon Medical Supply Co., Ltd.	
<b>Address:</b>	No.18 Jirong Road, Shenkeng, Henggang Street, Longgang District, 518173 Shenzhen, P.R. China	
<b>SRN (Single Registration. Number) :</b>	CN-MF-000018400	
<b>EC Representative:</b>	WellKang Ltd.	
<b>Address:</b>	Enterprise Hub, NW Business Complex, 1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, UK	
<b>SRN (Single Registration. Number) :</b>	XI-AR-000001836	
<b>We, the manufacturer, declare under our sole responsibility that</b>		
<b>the medical device(s)</b>	<b>Product Name</b>	Sterile High-pressure Angiographic Syringes for Multi-use
	<b>Type/model</b>	See attached tables for details
<b>of class</b>	according to Rule 2 indent 1 of Chapter III classification Rules of Annex VIII of regulation(EU) 2017/745	<b>Class IIa</b>
<b>Basic UDI-DI</b>	69383279201X9: 200ml, 24h 69383279202XB: 200/200ml,24h 69383279211XC: 200ml, 12h 69383279212XE: 200/200ml,12h	
<b>EMDN</b>	A0299- SYRINGES - OTHER	
<b>Are in conformity with the relevant provisions and requirements of regulation (EU)2017/745</b>		
<b>Conformity assessment procedure</b>	MDR (EU)2017/745 Annex IX	
<b>Notified Body</b>	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland CE 0197	
<b>Certificate &amp; number</b>	HZ 2158141-1	



Signed on: 2023-8-21 Place: Shenzhen, Guangdong, China

Signature (on behalf of the manufacturer) :

吴昊

Name of authorized signatory: 吴昊

Position held in the company: General Manager

Official Seal:



This document is valid until 2028-07-02 (EC certificate validity date)

Product name: Sterile High-pressure Angiographic Syringes for Multi-use

Attached Table 1:

Boon Product No.	Guerbet Product No.	Specifications (ml)	Use time (hour)	Injection equipment Identification code	Imaging (Angiographic) technology code	Pressure value (psi)
371201	241825	200	12	Guerbet OPTIVANTAGE	CT	350
371202	241826	200/200	12	Guerbet OPTIVANTAGE	CT	350
372401	241828	200	24	Guerbet OPTIVANTAGE	CT	350
372402	241827	200/200	24	Guerbet OPTIVANTAGE	CT	350

Attached Table 2:

Guerbet Product No.	Product Description
241825	OptiVantage 12h CT Syringe-200ml
241826	OptiVantage 12h Dual CT Syringe-200ml
241828	OptiVantage 24h CT Syringe-200ml
241827	OptiVantage 24h Dual CT Syringe-200ml