



EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC



Manufacturer:	Shenzhen Boon Medical Supply Co., Ltd.		
Address:	No.18 Jirong Road, Shengkeng, Henggang Street, Longgang District, 518173 Shenzhen, P.R. China		
EC Representative: WellKang Ltd, Enterprise Hub, NW Business Complex, 1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, UK			
We, the manufacturer, declare under our sole responsibility that			
the medical device(s)	Product Name:	Sterile High-pressure Angiographic Syringes for Single-use	
	Type/model:	See attached table for details	
of class	according to annex IX of directive 93/42/EEC :	Class IIa	
Are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.			
Applied harmonised standards, national standards or other normative documents	EN ISO 14971:2012	EN ISO 10993-10:2013	EN ISO 11607-2:2020
	EN ISO 15223-1: 2016	EN ISO 10993-11: 2018	EN ISO 14644-1:2015
	EN 1041:2008	EN 62366:2015	EN ISO 14644-2:2015
	EN ISO 7886-2: 1997	EN 556-1:2001/AC:2006	EN ISO 14698-1:2003
	EN ISO 10993-1:2009/AC:2010	EN ISO 11135:2014	EN ISO 14698-2:2003
	EN ISO 10993-4: 2017	EN ISO 11737-1:2018	EN 20594-1: 1993
	EN ISO 10993-5: 2009	EN ISO 11737-2:2009	EN 1707: 1996
	EN ISO 10993-7:2008/AC:2009	EN ISO 11607-1:2020	EN ISO 13485: 2016
	EN ISO 8536-4:2013	EN 15986: 2011	
Conformity assessment procedure	MDD 93/42/EEC Annex V		
Notified Body (name & number)	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Number: 0197		
Certificate & number	DD 60149848 0001		
Signed on:2021-12-20 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 2024-05-26 (EC certificate validity data) .			

Sterile High-pressure Angiographic Syringes for Single-use Attached Table:
Model: Type I, Type II

Brand Specification	BOON Product No.	Guerbet Product No.
200ml	100104 300112	800096B 800099B 844021B 800096S 800099S 844021S 900105S
150ml	300103	900103B 900103S
60ml	200103	801801B
200/200ml	100114	844023B 844022B 844022S 844023S
60/60ml	200103	801800B
Accessories	400101 400102 400201 400202 600202 600102 700101 700102 700103	801106B 801107B 302050B 240002B 240003B 240005B 239947B 801196

