

EC DECLARATION OF CONFORMITY

Name and address of the firm	Shenzhen Jumper Medical Equipment Co., Ltd. D Building, No. 71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong, China Post Code: 518103
We declare under our sole responsibility that	
the medical device	Fetal Doppler JPD-100S, JPD-100S(mini), JPD-100S+, PD-100S4, JPD-100S5, JPD-100S9, JPD-200S, JPD-100A, JPD-100A2, JPD-100B, JPD-100B2, JPD-100B3, JPD-100B4, JPD-100B+, JPD-100E, JPD-100E2, JPD-100E+, JPD-100S6, JPD-100S6+, JPD-100S6-2
of class	Class IIa, Rule 10 According to the classification principle in Annex VIII of Regulation (EU) 2017/745
SRN	CN-MF-000014343
Basic UDI-DI	69517405SH01SC

meets all the provisions of the Regulation (EU) 2017/745 which apply to it.

Applied harmonised standards, national standards or other normative documents	EN ISO 15223-1:2021 / EN ISO 20417:2021 / EN ISO 14971:2019+ A11:2021
	EN ISO 10993-1:2020/ EN ISO 10993-5:2009 / EN ISO 10993-10:2023
	EN 60601-1:2006+A1:2013+A2:2021
	EN 60601-1-2:2015+A1:2021
	EN 60601-2-37:2008+A1:2015
	EN 60601-1-11:2015+A1:2021
	EN 60601-1-6:2010+A1:2015+A2:2021/ EN 62366-1:2015+A1:2020
	EN 62304:2006+A1:2015
EN ISO 13485:2016+A11:2021	

Conformity assessment procedure	This declaration of conformity is based on the Regulation (EU) 2017/745, Annex IX (I, III and TDA in Section 4).
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Notified Body (if consulted)	SGS FIMKO OY NB 0598
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European Representative	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
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Authorized Representative's SRN	DE-AR-000000087
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CE certificate No.	FI24/1008008
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2024-03-06 SHENZHEN

Manufacturer: Shenzhen Jumper Medical Equipment Co., Ltd.

Name and function

