


EC DECLARATION OF CONFORMITY

Manufacturer	CHANGZHOU DSB MEDICAL CO., LTD
	#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China
European Representative	Wellkang Ltd.
	The Black Church, St Mary's Place ,Dublin 7,D07 P4AX, Ireland
Product	Pediatric Urine Bag
	Models 4501、 4505、 4521、 4525
Classification	Class I, rule 1, according to Article 52(7) of Regulation (EU) 2017/745/
	Class I, Rule 1
Conformity Assessment Route	Annexes II and III of Regulation (EU)2017/745/
<p>We herewith declare that the above mentioned products meet the provisions of the Council Regulation (EU) 2017/745 for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.</p> <p>The declaration statement is required to include the national legislation of Sweden. European Communities Council Regulation (EU) 2017/745 as amended, concerning Medical Devices as transposed into the requirements of the Swedish national legislation LVFS 2003:11</p>	
Standards Applied	All applicable harmonized Standards (published in the Official Journal of the European Communities)
Basic UDI-DI	Refer to appendix

Place Effective Date	Changzhou, Jiangsu Province, P.R. China 2021-04-23
Signature	
Name Position	Sunny Han MR

Appendix

REF	Package level	UDI-DI
4501	Inner label	06972642570026
	Shipping label	16972642570023
4505	Inner label	06972642570033
	Shipping label	16972642570030
4521	Inner label	06972642570064
	Shipping label	16972642570061
4525	Inner label	06972642570071
	Shipping label	16972642570078