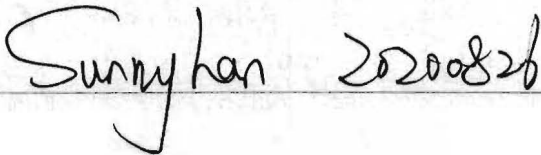


# Declaration of Conformity

Manufacturer				
Company Name		CHANGZHOU DSB MEDICAL CO., LTD		
Address		#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China		
European Representative				
Representative Name		Wellkang Ltd.		
Address		The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland		
Conformity Assessment				
Notified Body	EC Certificate(s)	Identification Number	Certification Date	Certificate Expiry Date
Intertek Semko AB	MDD Annex V cert. No.41377404	0413	14 July 2019	27 May 2024
Registration Information				
Notified Body Name		Intertek Semko AB		
Address		Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden		
Product Information				
Product No.	Description	Classification	Standards Applied	
4531	Urine specimen collection bag sterile, 200ml (100pcs)	Class 1s, Rule 1	EN ISO 13485:2016	
4511	Urine specimen collection bag sterile, 200ml (100pcs)			
4535	Urine specimen collection bag sterile, 100ml (100pcs)			
4515	Urine specimen collection bag sterile, 100ml (100pcs)			
4540	Urine specimen collection bag sterile, 10ml (100pcs)			
<p>DSB Medical declares that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC 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 Directive 93/42/EEC as amended, concerning Medical Devices as transposed into the requirements of the Swedish national legislation LVFS 2003:11 declares that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.</p>				
Name		Sunny Han		
Title		Management Representative		
Place of Issue		#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China		
Date of Issue		2020-08-26		
Signature				

# Declaration of Conformity

Manufacturer			
Company Name		CHANGZHOU DSB MEDICAL CO., LTD	
Address		#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China	
European Representative			
Representative Name		Wellkang Ltd.	
Address		The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland	
Conformity Assessment			
EC Certificate(s)	Certificate Number	Certification Date	Certificate Expiry Date
ISO 13485: 2016	0085778-01	09 Jul 2020	14 Jul 2023
Registration Information			
Notified Body Name		N/A	
Address		N/A	
Product Information			
Product No.	Description	Classification	Standards Applied
4501	Urine specimen collection bags non-sterile,200ml (100pcs)	Class 1, Rule 1	EN ISO 13485:2 016
4521	Urine specimen collection bags non-sterile,200ml (100pcs)		
4505	Urine specimen collection bags non-sterile,100ml (100pcs)		
4525	Urine specimen collection bags non-sterile,100ml (100pcs)		
<p>DSB Medical declares that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC 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 Directive 93/42/EEC as amended, concerning Medical Devices as transposed into the requirements of the Swedish national legislation LVFS 2003:11 declares that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.</p>			
Name		Sunny Han	
Title		Management Representative	
Place of Issue		#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China	
Date of Issue		2020-08-26	
Signature		