

Registration No.:

## EC Declaration of Conformity

### Directive 93/42/EEC Medical Devices

This is hereby declared that following designated product complied with the essential health and safety requirements of Council Directive 93/42/EEC Medical Devices on the approximation of the laws of the Member States relating to it.

Manufacturer			
Name	Weihai Dishang Medical Technology CO.,Ltd		
Address	Room 406-409,Block C,No.213 Torch Road,Torch High-tech Industrial Development Zone,Weihai,Shandong China		
Corporate representative	David Sun		
Declare that the products			
Name	Disposable Medical Surgical Mask		
Model	DS01-White/ DS02-Blue		
Standard	EN14683: 2019		
Classification	Type IIR		
Test Report No.	SL52025233855601TX	UMDN code	12-458
Single Registration number	DE/CA20/01-Luxuselbenswelt-318/20	GMDN code	35177

The conducted tests are documented in the test report number SL52025233855601TX prepared by SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

This declaration of conformity is issued under the sole responsibility of Weihai Dishang Medical Technology Co.Ltd. The declaration is supported by the Quality System approval to ISO 13485 issued by Benchmark Certification (Shanghai) Co. Ltd. with the certificate code BMCMDQ0120003M.

The Conformity Assessment Route used follow the Annex II, Annex III and Article 19 of the (EU) MDR 2017/745 The Registration Notification.

Luxus Lebenswelt GmbH has been appointed as Authorized European Representative according to Medical Device 93/42/EEC(MDD)

Sign:



*Eric Wei*

Position: Director

Date Of Issue:2020/08/18