

EU Declaration of Conformity
TO REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

Manufacturer	Name: Zhuhai Linte Medical Instrument Co., Ltd. Address: 4th Floor, Building 1, No.66, Yongda Road, Hongqi Town, Jinwan District, 519090 Zhuhai, Guangdong, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000012803		
Authorised Representative	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany SRN: DE-AR-000000001		
Product Name	Multi-parameter Monitor		
Trade Name	Multi-parameter Monitor		
Model	LT-M10, LT-M12		
CND Code	Z120302 VITAL SIGNS MONITORING INSTRUMENTS		
GMDN Code	33586 Single-patient physiologic monitoring system		
Basic UDI-DI	LT-M10: 697288788M10WL LT-M12: 697288788M12WQ		
Device Photograph	Please refer to 1.9.1 Device photograph in MDR-MPM-LTM-04 Device Description and Specification.		
Intended Purpose	The Lintemed Multi-parameter Monitor is intended to be used for monitoring, displaying, reviewing, and storing of multiple physiological parameters including ECG, respiration (RESP), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), of single adult and pediatric patients. This monitor is to be used in healthcare facilities by clinical professionals or under their direction. It is not intended for helicopter transport or home use.		
Risk Class	Class IIb		
Classification Rule	Rule 10 in Chapter III of Annex VIII of the Regulation (EU) 2017/745		
Conformity Assessment Route	Chapter I and III of Annex IX of the Regulation (EU) 2017/745		
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.			
Applied Standards	See MDR-MPM-LTM-03 Applied Standard List		
Notified Body	Name: TÜV SÜD Product Service GmbH Address: Ridlerstrasse 65, 80339 München, Germany Phone: +49 (89) 50084261 Fax: +49 (89) 50084230 Email: ps.zert@tuev-sued.de		
Identification Number	0123		
(EC) Certificate(s)	G10 110029 002	Valid until	2027-12-28
Start of CE-marking	2023-01-03		
Place, Date of Issue	Zhuhai, Guangdong 2023-01-03		
Signature:	 Name: Ma Kehzeng Function: Management Representative		