

Declaration of Conformity

Manufacturer's Name and Address	Medtrum Technologies Inc. 7F, Building 8, No.200 Niudun Road,Free Trade Zone Shanghai 201203 China	
Manufacturer's SRN	CN-MF-000001942	
Authorized Representative's Name and Address	Medtrum B.V. Hallenweg 24, 5683 CT Best The Netherlands	
Authorized Representative's SRN	NL-AR-000000595	
Product Name	Continuous Glucose Monitoring System	
Product Model Number	MY-160	
Basic UDI-DI	69711236809337F	
EMDN code	Z120401	
Intended purpose	The Continuous Glucose Monitoring System is indicated for use in people (ages 2 to 75 years) with diabetes.The system is intended for single patient use. The Continuous Glucose Monitoring System is indicated for continuous monitoring of interstitial fluid glucose levels.	
Classification	Class IIb	
Conformity assessment Procedure	Medical device regulation (MDR) EU 2017/745 Annex IX	
EU Quality Management System Certificate Number	MDR 767470 R000	
Notified information	Body BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands	Identification number: 2797 
This declaration of conformity is issued under the responsibility of Medtrum Technologies Inc. The undersigned hereby declares, on behalf of Medtrum Technologies Inc., that the medical devices referenced in the EU declaration for Conformity meet the Regulation (EU) 2017/745.		
Signed on behalf of Medtrum Technologies Inc.		

Revision	1.2
Revision/Überarbeitung/revidering/révision/rewizja/rev isão/revizyon/revidiranje/revisija	
Signature	
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Name	Zhaoyun He
Name/Name/navn/nom/nazwa/nome/isim/ime/vārds	
Title	Management Representative
Title/Titel/titel/titre/tytuł/título/başlık/naslov/nosauku ms	
Place	Shanghai,China
Place/Ort/sted/lieu/miejsce/lugar/yer/mesto/vieta	
Date	2025-02-26
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