Declaration of Conformity

pursuant to Article 19 and Annex IV of Regulation (EU) 2017/745 on medical devices

ergoline
MOVING TO HEALTH

Manufacturer	**ergoline GmbH** Lindenstr. 5 72475 Bitz Germany	
SRN of manufacturer	DE-MF-000006402	
Device name	Blood Pressure Cuffs for ergoselect / ergometrics	
Basic-UDI-DI	40593580036V	
Device identification	Blood Pressure Cuffs for ergoselect 4/5/10/12	
	REF: 705.810 705.813 705.811 705.814 705.812	**Device name:** Blood Pressure Cuff, Standard Blood Pressure Cuff, Standard, Tube 2m Blood Pressure Cuff, large Blood Pressure Cuff, large, Tube 2m Blood Pressure Cuff, small
	Blood Pressure Cuffs for ergoselect 100/150/200/400/600/1000/1100/1200	
	REF: 705.088 705.089 705.090 705.091 705.092	**Device name:** Blood Pressure Cuff, Standard Blood Pressure Cuff, Standard, Tube 2m Blood Pressure Cuff, large Blood Pressure Cuff, large, Tube 2m Blood Pressure Cuff, small
	Blood Pressure Cuffs for ergometrics ER 900/ER 900L/ER900EL	
	REF: 701.884 701.885 701.886 701.887 701.892	**Device name:** Blood Pressure Cuff, Standard Blood Pressure Cuff, Standard, Tube 2m Blood Pressure Cuff, large Blood Pressure Cuff, large, Tube 2m Blood Pressure Cuff, small
Intended use	A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder to compress the upper arm.	
Risk class of the device in accordance with the rules set out in Annex VIII	Class I according MDR (EU) 2017/745 Annex VIII, Rule 1	
Conformity assessment procedure	On the basis of the technical documentation pursuant to Annex II of Regulation (EU) 2017/745.	
Common specification	Not applicable	

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This EU declaration of conformity is issued under the sole responsibility of the manufacturer. With the signature, it is stated that the device that is covered by the present declaration is in conformity with Regulation (EU) 2017/745 on medical devices.

This EU declaration of conformity is signed in the name of and on behalf of the manufacturer.

This EU declaration of conformity is valid until a revised declaration of conformity is issued.

Bitz, 2023-01-30

Andreas Maurer
Name

Signature

Director Quality Management / Regulatory Affairs