

EU Declaration of Conformity

Herewith we declare under our sole responsibility that the following Class I medical devices (acc. Rule 1, Annex VIII) comply with the Regulation (EU) 2017/745.

Based on the conformity assessment, the declaration of conformity was issued according to Annex IV of Regulation (EU) 2017/745. Due to risk class 1 and according to Article 52 (7) of Regulation (EU) 2017/745 the manufacturer is entitled to conduct the conformity assessment procedure independently. An evaluation by a notified body is not required.

The implemented Quality Management System fulfills the requirements of
EN ISO 13485:2016.

Produkt	Product	Intended use, Basic-UDI-DI
circaid kompressive Socke	circaid compression anklet	The compression system is designed to provide compression to the foot and ankle region for patients with venous and lymphatic disorders. - 4026398M0304050103018J
circaid kompressiver Unterziehstrumpf	circaid compressive undersock	

circaid juxtafit premium Unterschenkel	circaid juxtafit premium lower leg	The compression system is designed to provide compression to the leg for patients with venous and lymphatic disorders. - 4026398M030499010301FZ
circaid juxtafit essentials Unterschenkel	circaid juxtafit essentials lower leg	
circaid juxtafit essentials Oberschenkel mit Knie	circaid juxtafit essentials upper leg with knee	
circaid juxtafit premium Fußteil	circaid juxtafit premium afw	
circaid juxtafit premium interlocking Fußteil	circaid juxtafit premium interlocking afw	
circaid juxtafit premium Bein Mass	circaid juxtafit premium leg MTM	
circaid juxtacures Unterschenkel	circaid juxtacures lower leg	
circaid juxtalite Unterschenkel	circaid juxtalite lower leg	
circaid juxtalite Fußteil	circaid juxtalite afw	

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circaid juxtalite hd Unterschenkel	circaid juxtalite hd lower leg	<p>The compression system is designed to provide compression to the leg for patients with venous and lymphatic disorders.</p> <p>-</p> <p>4026398M030499010301FZ</p>
circaid reduction kit Unterschenkel	circaid reduction kit lower leg	
circaid reduction kit Knie	circaid reduction kit knee	
circaid reduction kit Oberschenkel	circaid reduction kit upper leg	
circaid reduction kit Fußteil, circaid customizable interlocking Fußteil, circaid anpassbares interlocking Fußteil	circaid reduction kit afw, circaid customizable interlocking afw	
circaid pac band Fußteil	circaid power added compression (pac band)	
circaid single band Fußteil	circaid single band afw	
circaid reduction kit Zusatzband	circaid reduction kit shelf strap	<p>Supporting band for application in combination with other circaid compression garments.</p> <p>-</p> <p>4026398M030499010301FZ</p>
circaid juxtafit premium Zusatzband	circaid juxtafit premium shelf strap	
circaid reduction kit Lobe Lifter	circaid reduction kit lobe lifter	<p>Supporting band for application in combination with another circaid compression garment.</p> <p>-</p> <p>4026398M030499010301FZ</p>
circaid reduction kit Erweiterung	circaid reduction kit extension	

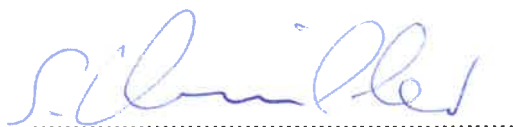
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circaid juxtafit essentials Arm	circaid juxtafit essentials arm	<p>The compression system is designed to provide compression to the arm for patients with venous and lymphatic disorders.</p> <p>-</p> <p>4026398M030499010302G3</p>
circaid juxtafit essentials Handteil	circaid juxtafit essentials hand wrap	
circaid juxtafit essentials Handschuh	circaid juxtafit essentials glove	
circaid reduction kit Arm	circaid reduction kit arm	
circaid reduction kit Handteil, circaid customizable Handteil	circaid reduction kit hand wrap, circaid customizable hand wrap	

SRN of the Manufacturer:	DE-MF-000007092
Common Specifications:	Not applicable.

We expressly state that the "registered"-sign "®" is not part of the name and is only used to identify a registered trademark, that is why it may appear at different positions.

Bayreuth, 24.01.2024



Stefan Weihermüller, PRRC medi GmbH & Co. KG



This declaration is valid until: 24.01.2027.

