Abelko
INNOVATION

Declaration of Conformity

Productname	Biomixer 550	Hemoscale AB-50
Productcode	BM550	AB-50
Product description:	Blood donation rocker	
Basic UDI-DI:	7350118260018B	
MDR class:	I	
Manufacturer:	Abelko Innovation Industrivägen 17 SE-972 54 LULEÅ SWEDEN	
SRN:	SE-MF-000008551	

This declaration is issued at the manufacturer's own responsibility according to:

EU law:	MDR 2017/745/EU WEEE 2012/19/EU RoHS 2011/65/EU	The Battery Directive 2006/66/EG The Packaging Directive 94/62/EG
Swedish law:	LVFS 2003:11	
Standards:	EN 60601-1:2006 (AC1, A1 A12) EN 60601-1-2:2015 EN 60601-1-6:2010 (A1)	EN ISO 14971:2019 EN 62366:2015 EN ISO 15223-1:2016 (2020) SS-EN 1041:2008 (A1) EN 60086-4:2007

The manufacturer’s management system has been reviewed and approved by Intertek Certification AB, P.O. Box 1103, SE-164 22 Kista, Sweden (number inside parentheses):

ISO 13485:2016 (#0105515-01)	ISO 9001:2015 (#17408) ISO 14001:2015 (#1422488)

The undersigned guarantees that the products above comply with the above legislation and standards.

Luleå 2022-12-14
Caroline Nordin, CEO