WaisMed®
A PerSys Medical Company

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Declaration of Conformity

We, WaisMed Ltd., hereby declare on our own responsibility that the distributed CE marked products, specified in the annex product list, meets the provisions of the Council Directive 93/42/EEC of June 1993, as amended by Directive 2007/47/EC, which apply to the products.

Conformity assessment was performed according to Annex II.

The conformity with the essential requirements set out in Annex I of the 93/42/EEC Directive has been demonstrated against the following harmonized standards: EN ISO 13485:2016, EN ISO 14971:2012, EN 62366-1:2015, EN ISO 10993-1:2009/AC:2010, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11737-2:2006, EN ISO 11607-1: 2017, EN ISO 11607-2: 2017, EN 1041:2008+A1:2013 and EN ISO 15223-1:2016.

The product(s) are covered by the "EC Certificate", reference number **ECM20MDD018 rev.1** delivered by **ENTE CERTIFICAZIONE MACCHINE SRL** (Via Ca' Bella, 243/A - loc. Castello di Serravalle, 40053 Valsamoggia, Italy) Notified Body Identification Number: **1282**.

Manufacturer	WaisMed Ltd. 10 Amal St. Afek Industrial Park, Rosh Ha'Ayin. Zip 4809234, Israel.
EU Authorized Representative	MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany

Place: Rosh Ha'Ayin, Israel

Date: December 22, 2020

Signature: WAISMED LTD 511937054

Roee Madai,
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Annex - Product List

Products Class: IIa
MDD Annex IX Rule: 7
Device Category: Bone injectors product line

List of Products	Device Codes		
	GMDN	NBOG	CND
B.I.G. Bone Injection Gun Adult	18009	MD 1101 MDS 7006	A010199
B.I.G. Bone Injection Gun Pediatric	18009	MD 1101 MDS 7006	A010199
NIO Intraosseous Device Adult	18009	MD 1101 MDS 7006	A010199
NIO Intraosseous Device Pediatric	18009	MD 1101 MDS 7006	A010199
NIO+ Adult Intraosseous Device	18009	MD 1101 MDS 7006	A010199
NIO Infant Intraosseous Device	18009	MD 0120 MDS 7006	A010199