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,
CEO, WaisMed

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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

Ente Certificazione Macchine

Notified Body n. 1282 - Testing Laboratory – Nr. 121697 PJLA
Authorized Training Body n. 6737 - Inspection Body

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES ACCORDING TO DIRECTIVE 93/42/EEC

REFERENCE N° 17/F

ENTE CERTIFICAZIONE MACCHINE SRL
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Waismed Ltd

Single Registration Number: IL-MF-000018893
Address: 10 Amal St., Industrial Park Rosh Ha'Ayin, Central Israel
Referent: Mr. Haim Bedani

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES
ACCORDING TO DIRECTIVE 93/42/EEC

Confirmation of the status of a formal application, written agreement, and appropriate surveillance activity in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Ente Certificazione Macchine srl (ECM), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1282 on NANDO**, confirms to have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and to have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with **Waismed Ltd**.

In addition, this letter confirms that **ECM**, where relevant, has signed a written agreement **Waismed Ltd**. governing transfer of the surveillance activitiy in accordance with Article 120, paragraph 3e of MDR as amended by Regulation (EU) 2023/607.

The devices covered by the formal application and the written agreements mentioned above are identified in the Tables below. **Table 1** identifies devices for which an MDR application has been received, written agreement concluded, and for which **ECM** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies devices for which an MDR application has been received and a written agreement concluded, but **ECM** has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR repectively, by 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

ENTE CERTIFICAZIONE MACCHINE SRL
LUCA BEDONNI

Table 1 Devices covered by this letter and for which ECM is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Intraosseous access device: B.I.G. Bone Injection Gun Adult, B.I.G. Bone Injection Gun Pediatric, NIO Intraosseous Device Pediatric, NIO Intraosseous Device Adult, NIO+ Adult Intraosseous Device, NIO I Intraosseous Device Infant	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☒ MDD/AIMDD Certificate ECM20MDD018 rev.1 issued by Ente Certificazione Macchine srl, NB number 1282 ☐ Not applicable

Table 2 Devices covered by this letter and for which ECM is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N.A.