Itamar Medical Ltd.

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Pneumatic Endo Probes – EU Declaration of Conformity

According to Annex IV of the Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017, concerning medical devices, we

Itamar Medical Ltd. (The Manufacturer)

Declare under our sole responsibility that the listed product:

12 Pneumatic Endo probes **(Catalog Number: AC1600005)**

Basic UDI-DI: 729010922AC16000ME

Intended use: The EndoPAT (EndoPATx/EndoPAT2000) device is a non-invasive device, intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.
The EndoPAT (EndoPATx/EndoPAT2000) device has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals.
The EndoPAT (EndoPATx/EndoPAT2000) device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

- Meets the provisions of the Regulation 2017/745 of 5 April 2017 concerning medical devices, which apply to the product.
- Conformity assessment was performed according to Annex IX (Chapther 1 & 3) of the Medical Device Regulation (QS certificate ISO 13485:2016 no. MD 685192).
- The product conform to product and production standards and common specifications listed in RDF068703 – List of Applied Standards EndoPATx.
- The product conforms to the general safety and performance requirements of the Medical Device Regulation.
- The product is classified as Class I, according to Rule 1 and Rule 13 in Annex VIII of the Medical Device Regulation.

Name and address of the Manufacturer	**Name and address of the Authorized Representative**
Itamar Medical LTD 9 Halamish St., P.O. Box 3579 Caesarea Ind. Park, 3088900 Israel	Arazy Group GmbH The Squaire 12 Am Flughafen 60549 Frankfurt am Main Germany
SRN - IL-MF-000012046	SRN - DE-AR-000007685

Name	**Title**	**Signature**	**Date of issue**	**Place of issue**
Moti Mikles	VP QA/RA &HCC		31-Mar-2023	9 Halamish St. Caesarea Ind. Park, 3088900, Israel

DOC Period of Validity (1 year from the date of issue): 31-Mar-2024

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