We

Name + address + Single Registration Number of manufacturer:	**Microtek Medical Malta Ltd.** **Sorbonne Centre F20 -Mosta Technopark** **MST 3000 Mosta** **Malta** **MT-MF-000012827**
Name + address + Single Registration Number of authorized representative:	Not Applicable

declare on our sole responsibility that

the medical device	Probe Covers
Type / Intended Use	A device intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gels) and/or to maintain the required hygienic level of various diagnostic or surgical procedures which utilize a transducer (probe).
Class Rule according to MDR Annex VIII	IIa Rule 7

Meets all the provisions of the Regulation (EU) 2017/745 on medical devices.

Notified body name, address, ID	DNV MEDCERT GmbH - Notified Body 0482 Pilatuspool 2, 20355 Hamburg, Germany
Conformity assessment procedure	MDR (EU) 2017/745 Annex IX
ID of the certificates issued	2620GB448250509
Common Specifications	Not applicable.
Validity	21 April 2028

Valid in conjunction with the batch related release documentation

Malta 15 Sep 2025	Marvic Debono
Place, date	Name and function (Person Responsible for Regulatory Compliance)

Signed on behalf of: **Microtek Medical Malta Ltd.**

Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
GENERAL PURPOSE PROBE COVER	Medline	General Purpose	PC1230EU	748426ML2APC09INE2KH
GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	Medline	General Purpose	PC1289PANNGEU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	Medline	General Purpose	PC1290NREU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	Medline	General Purpose	PC1291PANNGEU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	Medline	General Purpose	PC1416NREU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1288EU	748426ML2APP09INE2PLD
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1289EU	748426ML2APP09INE2PLD
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1289PANFEU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1290EU	748426ML2APC09INE2KH
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1291EU	748426ML2APP09INE2PLD
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1291PANFEU	748426ML2APC09INN2LC
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1296EU	748426ML2APP09INE2PLD
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1297EU	748426ML2APP09INE2PLD

GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1416EU	748426ML2APP09INE2PLD
GENERAL PURPOSE PROBE COVER KIT FEATURING ISOSILK	Medline	General Purpose	PC1419EU	748426ML2APP09INE2PLD
INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Medline	Intraoperative	PC1292NEU	748426ML2APC10INN2HN
INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Medline	Intraoperative	PC1308PANEU	748426ML2APC10INN2PAX
INTRAOPERATIVE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC1292EU	748426ML2APC10INE2GT
INTRAOPERATIVE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC1292PANEU	748426ML2APC10INN2PAX
INTRAOPERATIVE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC1295EU	748426ML2APP10INE2PH9
INTRAOPERATIVE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC1308EU	748426ML2APP10INE2PH9
LARGE T-SHAPED LATEX FREE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC4515EU	748426ML2APP10INE2PH9
LATEX FREE PROBE COVER KIT	Medline	Intraoperative	PC3787EU	748426ML2APC10INE2GT
SMALL T-SHAPED LATEX FREE PROBE COVER KIT FEATURING ISOSILK	Medline	Intraoperative	PC3687EU	748426ML2APP10INE2PH9
ULTRASOUND PROBE COVER KIT	Medline	General Purpose	4892080	748426ML2APC09INE2KH
ULTRASOUND PROBE COVER KIT	Medline	General Purpose	4892081	748426ML2APC09INE2KH