We declare on our sole responsibility that

Name + address + Single Registration Number of manufacturer:	**Microtek Medical B.V.** **Hekkehorst 24** **7207 BN Zutphen** **The Netherlands** **NL-MF-000006754**
Name + address + Single Registration Number of authorized representative:	Not Applicable

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. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Notified body name, address, ID	DNV MEDCERT GmbH Notified Body Pilatuspool 2, 20355 Hamburg, Germany 0482
Conformity assessment procedure	MDR (EU) 2017/745 Annex IX
ID of the certificates issued	6067GB448250411
Common Specifications	Not applicable
Validity	14 May 2028

Valid in conjunction with the batch related release documentation

Mosta, 14-May-2025	Marvic Debono Person Responsible for Regulatory Compliance
Place, date	Name and function (Person Responsible for Regulatory Compliance)

Signed on behalf of: **Microtek Medical B.V.**

Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
Probe Covers	Medline	Endocavity	503140	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	503141	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	503189	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	503190	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	503191	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	503193	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	503195	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	503197	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	503198	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	503199	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	583141	748426MB2APC23INN29E
Probe Covers	Medline	Endocavity	86450	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86582	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86590	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86592	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86593	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86595	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86596	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86599	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86602	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86607	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86608	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86609	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86613	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86614	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86616	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86630	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86631	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86632	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86650	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86654	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86662	748426MB2APC23INN19C

Probe Covers	Medline	Endocavity	86663	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86664	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86666	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86670	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86673	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86674	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86676	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86678	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86679	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86681	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86683	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86687	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86689	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86693	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86694	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86696	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86697	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86698	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86704	748426MB2APC23INN19C
Probe Covers	Medline	Endocavity	86706	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	86720	748426MB2APC23INR19Q
Probe Covers	Medline	Endocavity	87105	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	87106	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	87110	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	87111	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	87114	748426MB2APC23INR29S
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Probe Covers	Medline	Endocavity	88613	748426MB2APC23INN29E
Probe Covers	Medline	Endocavity	88632	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	88654	748426MB2APC23INN29E

Probe Covers	Medline	Endocavity	88660	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	88662	748426MB2APC23INN29E
Probe Covers	Medline	Endocavity	88663	748426MB2APC23INN29E
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Probe Covers	Medline	Endocavity	88681	748426MB2APC23INR29S
Probe Covers	Medline	Endocavity	88704	748426MB2APC23INN29E
Probe Covers	Medline	Endocavity	88720	748426MB2APC23INR29S
Probe Covers	Medline	General Purpose	86612	748426MB2APC23INN19C
Probe Covers	Medline	General Purpose	86653	748426MB2APC23INN19C
Probe Covers	Medline	General Purpose	86684	748426MB2APC23INN19C
Probe Covers	Medline	General Purpose	86715	748426MB2APC23INN19C
Probe Covers	Medline	General Purpose	86797	748426MB2APC23INN19C
Probe Covers	Medline	General Purpose	88612	748426MB2APC23INN29E
Probe Covers	Medline	General Purpose	88653	748426MB2APC23INN29E
Probe Covers	Medline	General Purpose	88684	748426MB2APC23INN29E
Probe Covers	Medline	General Purpose & Intraoperative	86603	748426MB2APC23INR19Q
Probe Covers	Medline	General Purpose & Intraoperative	86604	748426MB2APC23INR19Q
Probe Covers	Medline	General Purpose & Intraoperative	86610	748426MB2APC23INR19Q
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Probe Covers	Medline	General Purpose & Intraoperative	86651	748426MB2APC23INR19Q
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Probe Covers	Medline	General Purpose & Intraoperative	86656	748426MB2APC23INR19Q
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Probe Covers	Medline	General Purpose & Intraoperative	86675	748426MB2APC23INR19Q
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Probe Covers	Medline	General Purpose & Intraoperative	88686	748426MB2APC23INR29S
Probe Covers	Medline	General Purpose & Intraoperative	88694	748426MB2APC23INR29S
Probe Covers	Medline	General Purpose & Intraoperative	88703	748426MB2APC23INR29S
Probe Covers	Medline	Intraoperative	16565	748426MB2APC23INR29S