Certificate of Conformity

Name of Manufacturer:	**Micronic Manufacturing B.V.**
Address of Manufacturer:	**Platinastraat 51** **8211 AR Lelystad** **THE NETHERLANDS**

We hereby declare under our sole responsibility that the following product(s):

Article number:	Article description:
MP53000	Pierceable TPE Capmat Natural for capping 96 tubes
Production Batch:	

to which this declaration relates is in conformity with the following standards.

GENERAL

Production facilities
Micronic has three production sites which below are referred to as 'Micronic':

Micronic Manufacturing B.V.		Micronic Manufacturing USA LLC
Platinastraat 51 8211 AR Lelystad The Netherlands	Platinastraat 4 8211 AR Lelystad The Netherlands	210 Bridgewater RD Suite 3 Aston, Pennsylvania United States of America

ISO 9001
Micronic operates a corporate integrated Quality Management System (QMS) that is certified to ISO 9001:2015.

ISO 14001
Reducing our impact on the environment is an integral part of our continuous improvement efforts. The environmental policy of Micronic is determined by our headquarters in the Netherlands, which is certified to ISO 14001:2015.

LABWARE

Class 7 clean room production
The labware is manufactured and assembled in-house in a NEN-EN-ISO 14644-1 Class 7 certified clean room environment (which is comparable to the US Federal Standard 209E Class 10,000).

Virgin material and approvals
For the manufacturing of its long term sample storage labware products Micronic uses solely virgin plastic raw material. The raw materials and auxiliary agents are selected based on the specifications that satisfy the high quality requirements of our products. The materials are FDA approved and comply with the (USA) USP XXII tests, including class VI (Medical approved), and the European Pharmacopoeia-monograph 3.2.2 unless communicated otherwise. Material components used to produce Micronic labware can be traced via the lot number indicated on the packaging.

Extractables
The materials used for Micronic tubes are the result of extensive research. One selection criterion is that no measurable amount of extractables should leach into samples.

RNase, DNase and endotoxin (pyrogen)
By maintaining the highest possible hygiene level during our production processes, Micronic manufactured labware is free of any detectable RNase or DNase contamination and the endotoxin level of produced and packaged labware is limited to an acceptable minimum (< 0.01 EU/ml). Our products are periodically tested on RNase, DNase and their endotoxin levels by independent expert organizations.

Laser-etched codes
The Micronic 2D Data-Matrix codes and 1D barcodes are produced conform industry standards. The 2D Data-Matrix code (which adheres to the ECC200 standard) and 1D barcode (type 128B) are laser-etched into the code area and are guaranteed unique.

Product quality control
Products produced by Micronic are tested according to AQL inspection level G2 and AQL value 0.4.

CE marking
Micronic labware products comply with the CE label Class 1. In this respect the European Directive 98/79/EC (In Vitro Diagnostic Medical Devices) is the leading standard.

Sterilization
Micronic products can be supplied gamma irradiated (upon request in compliance with ISO 11137 Sterilization of Health Care Products (radiation) / 15 kGy Avg.) or ethylene oxide treated (upon request in compliance with ISO 11135 Sterilization of Health Care Products (ethylene oxide) and ISO 10993-7 regarding EO residual limits).

IATA
Our products comply with the IATA requirements for the transport of diagnostic specimens (UN packing instruction 602 and 650), assuming that our products are properly used (closed).

Shelf life
At room temperature the shelf life of our products is 10 years (for gamma irradiated products 5 years).

Place of issue: Lelystad, The Netherlands Date of issue: 2020-06-12

Patrick van Wijk
General Manager Micronic Manufacturing B.V.