



Declaration of Conformity

- Manufacturer:** Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA
- Description:** Eclipse® and Eclipse® 3D Ultrasound Probe Covers
- Classification:** Class I transient, invasive, non-active, non-sterile per REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 Annex VIII Chapter 3 Rule 5
- EC Representative:** Parker Laboratories BV
Bedrijvenpark Twente 305
7602 KL Almelo
The Netherlands
- Intended Use:** Eclipse Probe Covers are disposable probe covers for use with medical ultrasound probes/transducers.
- Products:** See table below

Product Description	Product Refs	Basic UDI-DI
Eclipse Ultrasound Probe Covers	38-01	085568300638000K5
Eclipse 3D Ultrasound Probe Covers	38-03	085568300638000K5

These products are manufactured in compliance with the following standards:

- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN 1041:2008 Information Supplied by the Manufacturer with Medical Devices
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity

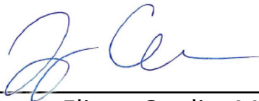
Standards (cont.):

- ISO 10993-10:2012 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
- ASTM D3492-89: Standard Specification for Rubber Contraceptive (modified to suit non-latex probe covers)
- ASTM Method F 1670 Synthetic Blood Penetration
- ASTM Method F 1671 Viral Penetration
- Anti-Microbial Preservative Efficacy per USP 51

Parker Laboratories, Inc., being a manufacturer of medical devices sold within the European Union, hereby declares that the products covered by this declaration conform to the Essential Requirements of EC Directive (EU) 2017/745.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Parker Laboratories, Inc.

Signature:



Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

26 Feb 2021

Date