ESI, Inc.

Declaration of Conformity

Name and address of the manufacturer:

ESI, Inc.
2915 Everest Lane
Plymouth, MN 55447

We declare under our sole responsibility that the medical device: **ClearScan® Non-Sterile Ophthalmic Ultrasound Probe Cover**

Product name: CS250 UDI Device ID: B360CS25000

Classified into class I per rule 5 according to annex VIII of the Medical Devices Regulation (EU) 2017/745.

Intended use: The ClearScan® Ophthalmic Ultrasound Probe Cover is an eye contact invasive transient use device.

The ClearScan® Cover is in conformity with the following standards or other normative documents:

EN 10993, Biocompatibility;
EN 1041:2008, Information supplied by the manufacturer with medical devices;
EN 980: 2008, Required Symbols;
EN 13485:2016 Quality Systems;
Regulation (EU) 2017/745 on medical devices~~,~~

A Technical File is available in English to European Competent Authorities.
The corresponding instruction sheet is available in English and Spanish.
Further languages are provided upon request according to the current regulations.

June, 28 2023

Thomas A. Burba
Chief Operating Officer
ESI, Inc.

European Authorized Representative

Viu2020. SL
Ribes 87, bajos
08013 Barcelona, España