

EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer, Canfield Scientific, Inc. The objects of this declaration described below meet the provisions of the applicable annexes of the following regulations and directives.

Product Description:

The DermaGraphix IntelliStudio System is a photo-documentation system intended for documenting aspects of the patient's exposed skin surface.

Objects of Declaration:

Product Name:	Model:
DermaGraphix IntelliStudio 120V	51958
DermaGraphix IntelliStudio 230V	51959
DermaGraphix IntelliStudio 120V, Extra Monitor	51963
DermaGraphix IntelliStudio 230V, Extra Monitor	51964

Basic UDI-DI: 12400000050DERMISTUDIOVF

Manufacturer: Canfield Scientific Inc
4 Wood Hollow Rd
Parsippany, NJ 07054

Authorized Representative: Canfield Scientific GmbH
Otto-Brenner-Str. 203
D-33604 Bielefeld
Germany

Classification per MDR Annex VIII: Class I (Rule 1, Rule 13)

Regulations, Directives, and Standards:

(EU) 2017/745 Medical Device Regulation (MDR)

EN 60601-1:2006 + A1:2013 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015 - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

EN 60601-1-6:2010 + A1:2015 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

EN 62366-1:2008 + A1:2015 - Medical devices – Application of Usability Engineering to medical devices

EN 62304:2006 + A1:2015 - Medical device software - Software Life Cycle Process

EN ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes

EN 14971:2019 - Medical devices — Application of risk management to medical devices

Signed for and on behalf of Canfield Scientific, Inc.

Doug Canfield		Parsippany, NJ	6/4/2021
President, Canfield Scientific, Inc.	Signature	Place	Date