

## **EU Declaration of Conformity**

in accordance with Directive (EC) 93/42/EEC on Medical Devices

Manufacturer: Carl Zeiss Meditec, Inc., 5160 Hacienda Drive, Dublin 94568, CA, USA

We, Carl Zeiss Meditec, Inc., herewith declare under our sole responsibility that the following Medical Device meets the Requirements of the European Directive 93/42/EEC.

**Product identification:** 

UMDNS: Ophthalmic Perimeters, Automated

GMDN: Perimeter, Automatic

Medical Device Name / Trade Name:

Humphrey Field Analyzer 3 (HFA3)

Models/Reference:

830, 840, 850, 860

Accessories:

Table

**Medical Device Class** 

Class IIa

**Conformity Assessment Procedure** 

Annex II of MDD 93/42/EEC

Scope of Application:

This Declaration of Conformity is valid for all products

manufactured until 2023-08-09

**UMDNS** classification:

16-918

**GMDN Code:** 

16918

**Notified Body:** 

DQS Medizinprodukte GmbH, August-Schanz-Straße 21,

60433 Frankfurt - notified under 0297.

**Certificate Registration Number:** 

250712 MR2

**Certificate Unique ID:** 

170716787

EU Representative:

Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52,

07745 Jena, Germany

Any modification to the product not authorized by Carl Zeiss Meditec, Inc. will invalidate this declaration.

Viet Nguyen

Director, Quality Management

**Document Number**: 2660021171871

& Quality Management Representative

Issuing Site: Carl Zeiss Meditec, Inc., 5160 Hacienda Drive, Dublin, CA 94568, USA

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