



2255 116th Avenue N.E., Bellevue, WA 98004-3039, USA

ISO13485

T: 425-455-5200 or 800-888-6616 · F: 425-462-6669 · E: contact@ocularinc.com · I: www.ocularinc.com

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

MANUFACTURER			
Name of Company		Address of Company	
Ocular Instruments, Inc.		2255 116th Ave NE Bellevue, WA 98004 USA	
		Manufacturer SRN	
		US-MF-000007216	
AUTHORIZED REPRESENTATIVE			
Authorized Representative		Address	
Emergo Europe		Westervoortsedijk 60 6827 AT Arnhem The Netherlands	
		AR SRN	
		NL-AR-000000116	
		Telephone/email	
		+31.70.345.8570 EmergoEurope@ul.com	
PRODUCT IDENTIFICATION			
Product Name		Code/Catalog Number	
Tonometer		See attached	
Intended Purpose		Basic UDI-DI (The Basic UDI-DI has been assigned in accordance with Article 27 of Regulation (EU) 2017/745.)	
Lenses are intended to briefly be placed on the eye by clinicians to assist in the estimation of intraocular pressure.		06302381262838	
RISK CLASS FOR DEVICES			
Class	Applicable Union Legislation	Other Regulatory References (if applicable)	Common Specifications/Standards
1	Regulation (EU) 2017/745 on medical devices (MDR)	FDA 21 CFR 800 (not applicable to MDR conformity; included for reference only)	ISO 13485:2016, ISO 14971:2019, ISO 10993-1:2018 + AMD1:2020, IEC 62366-1:2015 + AMD1:2020, ISO 15223-1:2021, ASTM D7386
Rule			
5			
NOTIFIED BODY			
Notified Body		Notified Body ID Number	
Not Applicable (Class 1)		Not Applicable (Class 1)	
Route to Compliance		CE Certificate Number	
NA		Not Applicable (Class 1)	

Ocular Instruments, Inc. hereby declares, under its sole responsibility, that the medical devices identified in this Declaration of Conformity (including the product codes listed in the attached pages) conform to Regulation (EU) 2017/745 on medical devices. The devices meet the applicable General Safety and Performance Requirements (GSPRs) of Annex I to Regulation (EU) 2017/745. The manufacturer has established and maintains technical documentation in accordance with Annex II and Annex III to Regulation (EU) 2017/745. This Declaration of Conformity is issued in accordance with Article 19 and Annex IV of Regulation (EU) 2017/745.

Signed for and on behalf of the manufacturer:

Representative: Staci Caldwell

Title Quality Manager

Signature

Place Bellevue, WA USA

Date

09-Feb-26

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

Product Code	Long Description	Stock Code	GMDN
OBBT	Barron Barraquer 65-90mm Hg Tonometer	6750	32721
OBT-65	Barraquer 65mm Hg Tonometer	4801	32721
OBT-65-90	Barraquer 65-90mm Hg Tonometer	6143	32721
OBT-O	Barraquer O-Ring Tonometer	5347	32721
OBT-TC-10-15	Terry Scale Barraquer 10-15mm Hg Tonometer	904	32721
OBT-TC-15-21	Terry Scale Barraquer 15-21mm Hg Tonometer	905	32721
OBVT	Varley Barrquer 90mm Hg Tonometer	6642	32721
OGBT-30-50	Griffin Barraquer 30-50mm Hg Tonometer	10172	32721
OKBT-20-30	Kasaby Barraquer 20-30mm Hg Tonometer	9979	32721