

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Intelon Optics, Inc	331 Montvale Ave 5 th floor, Woburn, MA 01801 USA	US-MF-000008283

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
MedEnvoy Global B.V.	Prinses Margrietplantsoen 33-Suite 123 2595 AM The Hague The Netherlands	NL-AR-000024028	+31.70.326.2148 EU-AR@medenvoyglobal.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
BOSS™	N/A
Intended Purpose	Basic UDI-DI
BOSS™ is a non-contact, confocal, high-resolution optical-scanning platform targeted at identifying intrinsic biomechanical properties of transparent ocular tissues, such as cornea and lens. BOSS™ provides ophthalmological professionals with corneal and crystalline lens analysis of elastic properties displayed as a map and individual axial scans. BOSS™ is used as an aid in identification of abnormalities in biomechanical properties of human eye. Professional use only.	860006306BOSS98

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	I	BS EN ISO 13485:2016/AC:2018
Rule:	13	

Intelon Optics, declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- RoHS Directive 2011/65/EU and RoHS 3 (EU 2015/863)

COMPANY REPRESENTATIVE: Dimitri Chernyak

TITLE: COO

SIGNATURE:



PLACE: Woburn, MA

DATE: 03/16/2023