Declaration of Conformity

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
AdDent, Inc.	43 Miry Brook Road Danbury, CT 06810 USA	US-MF-000019453

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
Microlux Protective Sleeve	600027
Intended Purpose	**Basic UDI-DI**
The Microlux Protective Sleeve is an accessory for the Microlux family of Transilluminator units. It is a single patient use disposable barrier intended to be placed over a Microlux Transilluminator unit to help prevent cross contamination.	++D869600027A4

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	ISO 9001:2015 certified, ISO 13485:2016 compliant, EN ISO 14971:2012
Rule:	5	

AdDent, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Dr. Joshua Friedman

TITLE: President

SIGNATURE:



PLACE: Danbury, CT USA

DATE: August 1, 2022