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**
Bio/Screen Oral Exam light	110090
Intended Purpose	**Basic UDI-DI**
The Bio/Screen Oral Exam light is intended to be used by a dentist or health care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities and aid in defining lesion borders.	++D8691100908M

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	ISO 9001:2015 certified, ISO 13485:2016+AC:2018 compliant, ISO 14971:2012, ANSI/AAMI/IEC 60601-1, EMC ANSI/AAMI/IEC 60601-1-2, IEC 62471:2006
Rule:	13	

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

- Medical Devices Regulation (EU) 2017/745
- RoHs (EU) 2015/863

COMPANY REPRESENTATIVE: Dr. Joshua Friedman

TITLE: President

SIGNATURE:



PLACE: Danbury, CT USA

DATE: April 08, 2022