# 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<br>Danbury, CT 06810 USA | US-MF-000019453 |

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

| PRODUCT IDENTIFICATION | |
|---|---|
| **Product Name** | **Code / Catalog Number** |
| Compex HD | 130000 |
| **Intended Purpose** | **Basic UDI-DI** |
| The Compex HD unit is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre-Loaded Tip) to 155˚F (68˚C). | ++D8691300008G |

| RISK CLASS FOR DEVICES | | |
|---|---|---|
| **Device Classification** | | **Common Specifications / Standards** |
| **Class:** | I | ISO 9001:2015 certified, ISO 13485:2016+AC:2018 compliant<br>ISO 14971:2012<br>ANSI/AAMI/IEC 60601-1, EMC ANSI/AAMI/IEC 60601-1-2 |
| **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:** May 05, 2022