



## EU Declaration of Conformity - Medical Device Directive

Product:

Dental Equipment

This declaration of conformity is issued under the sole responsibility of:

A-dec, Inc.  
2601 Crestview Dr.  
Newberg, Oregon, 97132 USA

This product is in conformity with the applicable requirements of the following relevant Union harmonisation legislation:

The Class IIa products specified in this document conform to the design, manufacturing and final inspection of the Medical Device Directive (93/42/EEC) Annex II, Full Quality Assurance System, as transposed into national legislation in EEA member states.

The Class I products specified in this document conform to the design, manufacturing and final inspections of the Medical Device Directive (93/42/EEC) Annex VII, as transposed into national legislation in EEA member states.

2011/65/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Standard(s) for which conformity is declared:

Applicable sections of EN 1640 and other normative standards as they apply.

Quality Management System:

The product specified conforms to ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes.

Name and address of Authorised Representative:

Donawa Lifescience Consulting SRL  
Piazza Albania, 10  
00153 Rome, Italy



*EC Certificate No. 1434-MDD-432/2020*

***Class I - Products***

ICX Waterline Treatment Tablets

***Class IIa - Products***

Dental Delivery Systems

Assistant's Instrumentation

Assistant's Cart Instrumentation

Doctor's Cart Delivery Systems

(See attached list for model numbers and/or descriptions)

A-dec, Inc. declares under our sole responsibility that the equipment specified above conforms to the listed directives and standards, when installed in accordance with installation instructions contained in the product documentation.

\_\_\_\_\_  
Kendra Rathkey

Director of Regulatory Affairs

A-dec, Inc.

Dated: 2021-03-03



## Class I Products

<b>Equipment Type</b>	<b>Model</b>	<b>Product Description</b>
<b>ICX Waterline Treatment Tablets</b>	90.1064.00	A-dec ICX Water Treatment Tablet 0.7 Liter
	90.1065.00	A-dec ICX Water Treatment Tablet 2.0 Liter



## Class IIa Products

Equipment Type	Model	Product Description
<b>Dental Delivery Systems</b>	200	Dental Delivery System
	332	Traditional-Style Radius Dental Delivery System
	333	Continental-Style Radius Dental Delivery System
	334	Traditional-Style Dental Delivery System
	335	Continental-Style Dental Delivery System
	336	Traditional-Style Dental Delivery System
	342	Wall-Mount Dental Delivery System
	532	Traditional-Style Dental Delivery System
	533	Continental-Style Dental Delivery System
	541	12 O'Clock Duo Dental Delivery System
	542	Side Dental Delivery System
	4631	Duo Dental Delivery System
	8000	Performer Dental Delivery System
	8100	Performer Dental Delivery System
<b>Assistant's Instrumentation</b>	200	Assistant's Instrumentation w/ Support Center
	351	Radius Assistant's Arm Instrumentation
	352	Assistant's Arm Instrumentation
	353	Assistant's Arm Instrumentation
	551	Assistant's Arm Instrumentation
	545	12 O'Clock Assistant's Instrumentation
	4635	Assistant's Instrumentation
	8000	Performer Assistant's Instrumentation
	8500	Performer Assistant's Instrumentation
<b>Assistant's Cart Instrumentation</b>	2615	Cascade Assistant's Cart Dental Delivery System
	7004	Cart-Pac Assistant's Instrumentation
<b>Doctor's Cart Delivery Systems</b>	2561	Decade Duo Cart Dental Delivery System
	2562	Decade Doctor's Cart Dental Delivery System
	2671	Cascade Duo Cart Dental Delivery System
	3420	PAC 1 Field Unit Dental Delivery System
	3420	PAC 1 Institutional Unit Dental Delivery System



## Class IIa Medical Products Accessories

Equipment Type	Model	Product Description
Dental Saliva Ejector (SE)		Autoclavable Saliva Ejector
High Volume Evacuator (HVE)		Autoclavable QD HVE Autoclavable High Volume Evacuator Tips Non-Autoclavable High Volume Evacuator Tips
Dental Air/Water Syringe	200	Dental Air/Water Syringe Autoclavable Air/Water Syringe, Traditional Autoclavable Air/Water Syringe, Continental Autoclavable Air/Water Syringe, Warm Water
Tooth Dryer		Autoclavable Tooth Dryer
Dental Electric Motor	EA-53 NLX Plus NLX Nano NLZ	A-dec Electric Motor A-dec Electric Motor A-dec Electric Motor A-dec Electric Motor
Dental Unit Waterline Shock Treatment	90.1691.00 90.1691.01	ICX Renew, Case ICX Renew, Carton