



# CERTIFICATE

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

**Full Quality Assurance System  
Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**A-dec, Inc.**

**2601 Crestview Dr.  
Newberg, Oregon 97132 UNITED STATES**

for the design, manufacture and final inspection of medical devices, class: Class IIa

**Dental delivery systems and chair mounted dental delivery  
systems including electric motors, dental unit waterline  
treatment products**

*The list of medical devices covered by this certificate is provided in the Annexes 1, 2, 3*

**complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law, as evidenced by the audit conducted by the PCBC**

Validity of the Certificate: from 11.12.2020 to 27.05.2024

The date of issue of the Certificate: 11.12.2020

The date of the first issue of the Certificate: 09.04.2019



Issued under the Contract No. MD-44/2020  
Application No: 509/2020  
Certificate bears the qualified signature.  
Warsaw, 11/12/2020  
Module H2/3/4/5  
FBM-26-E\_9

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.12.11  
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**Vice-President**



## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-432/2020**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Dental delivery system	Dental delivery system	A-dec 200 Dental Delivery System
		A-dec 332 Dental Delivery System
		A-dec 333 Dental Delivery System
		A-dec 334 Dental Delivery System
		A-dec 335 Dental Delivery System
		A-dec 336 Dental Delivery System
		A-dec 342 Dental Delivery System
		A-dec 532 Dental Delivery System
		A-dec 533 Dental Delivery System
		A-dec 541 Dental Delivery System
		A-dec 542 Dental Delivery System
		A-dec 8000 Performer Dental Delivery System
		A-dec 3072 Cascade Dental Delivery System
		A-dec 4631 Duo Dental Delivery System
A-dec 2561 Decade Duo Cart Dental Delivery System		



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Anna  
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Wyroba

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podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.12.11  
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**Vice-President**



## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-432/2020**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Dental delivery system	Dental delivery system	A-dec 2562 Decade Doctor's Cart Dental Delivery System
		A-dec 2671 Cascade Duo Cart Dental Delivery System
		A-dec 3420 PAC 1 Field Unit Cart Dental Delivery System
		A-dec 3420 PAC 1 Institutional Unit Cart Dental Delivery System
	Dental Assistant's Instrumentation	A-dec 200 Assistant's Instrumentation
		A-dec 351 Assistant's Instrumentation
		A-dec 352 Assistant's Instrumentation
		A-dec 353 Assistant's Instrumentation
		A-dec 551 Assistant's Instrumentation
		A-dec 545 Assistant's Instrumentation
		A-dec 8000 Performer Assistant's Instrumentation
		A-dec 4635 Assistant's Instrumentation
		A-dec 2615 Cascade Assistant's Cart Dental Delivery System
		A-dec 7004 Cart-Pac Assistant's Instrumentation



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Vice-President

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Małgorzata Wyroba  
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## ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-432/2020**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Dental Delivery System Accessory	Dental Electric Motor	Electric Motor System: NLZ, NLX, EA-53
	Dental Air/Water Dental Syringe	Dental Air/Water Dental Syringe
	High Volume Evacuator (HVE)	High Volume Evacuator (HVE)
	High Volume Evacuator (HVE)	High Volume Evacuator (HVE) Tips
	Saliva Ejector (SE)	Saliva Ejector (SE)
	Tooth Dryer	Tooth Dryer
Dental Unit Waterline Treatment Products	Dental Unit Waterline Shock Treatment	ICX Renew



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Małgorzata Wyroba  
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