EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Legal Manufacturer:	Young Dental Manufacturing Co. 1, LLC dba Biotrol dba Denticator
Legal Manufacturer Address:	13705 Shoreline Court East Earth City, Missouri 63045 USA
Eudamed SRN:	US-MF-000027132
Technical Document Number:	TF-EC-003
Declaration of Conformity Number:	DOC-EC-003
Declaration of Conformity Issue Date:	13-MAY-2025

We the manufacturer Young Dental Manufacturing, declare that the products named and listed in this Declaration of Conformity meet the provisions of this Council Regulation which apply to them, and the CE mark may be affixed.

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

Product Classification:	IIa
Product Family:	Disposable Prophylaxis Angle
Product Family Intended Use:	Used to clean and polish teeth.
Common Specifications:	Not applicable, device meets requirements through harmonized standards, see Technical Document.
Sterile:	No
Measuring Function:	No
Regulation Classification and Rule #	Annex VIII Rule 5

Notified Body (Name and Identification Number):	ICIM S.p.A. 0425 P.zza Don E. Mapelli, 75 - 20099 Sesto San Giovanni (MI) Italy

Conformity Assessment Procedure:	Annex XI Part A
CE Certificate Number:	0425-MDR-030130-00

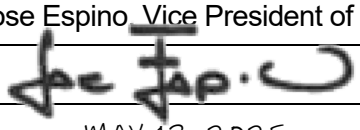
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Declaration of Conformity

EU Representative (Name and Address):	Young Microbrush Ireland Ltd. Clogherane, Dungarvan, Co. Waterford, X35 VE02, Ireland SRN: IE-AR-000011249

The undersigned authorized person signing for and on behalf of: Young Dental Manufacturing

Printed Name and Title: Jose Espino, Vice President of Quality & Regulatory Affairs

Signature: 

Date: MAY 13, 2025

Revision History

Date of Revision	Description of Change	Significance of Change
13-MAY-2025	Update DOC to MDR in latest template. Merge parts listed in all DOCs (DOC-EC-001, DOC-EC-006, DOC-EC-008) as they all fall under 1 Young Dental Technical File. Change EC Rep and Notified Body. Add Basic UDI. Remove obsolete parts: 580014, 580050, 131520, 295330, 295332, 296002, 296003, 296004, 296005	Non-significant, no change to devices covered under this DOC.

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Product Family Item Number Listing

Product Number	Product Description	Basic UDI
514610	Perfect Choice® DPA	03027346938K780752EGSK4
514650	Perfect Choice® DPA	03027346938K780752EGSK4
295463	Denticator® Eco Disposable Prophy Angle	03027346938K780752EGSK4
295464	Denticator® Eco Disposable Prophy Angle	03027346938K780752EGSK4
296166	DPA, Denticator Eco Slim Contra, Light Gray, Web, Short, 125ct	03027346938K780752EGSK4
296167	DPA, Denticator Eco Slim Contra, Light Gray, Web, Short, 1000ct	03027346938K780752EGSK4
500014	DPA Teal w/ Regular White Diamond Cup	03027346938K780752EGSK4
500050	DPA Teal w/ Regular White Diamond Cup	03027346938K780752EGSK4
500114	DPA Teal w/ Soft Pink Diamond Cup	03027346938K780752EGSK4
500150	DPA Teal w/ Soft Pink Diamond Cup	03027346938K780752EGSK4
500414	DPA Teal w/ Flat Prophy Brush	03027346938K780752EGSK4
500514	DPA Teal w/ Tapered Prophy Brush	03027346938K780752EGSK4
500572	DPA Teal w/ Tapered Prophy Brush	03027346938K780752EGSK4
501214	DPA Orig. Green w/ Regular White Cup	03027346938K780752EGSK4
501250	DPA Orig. Green w/Regular White Cup	03027346938K780752EGSK4
501314	DPA Orig. Green w/ Soft Green Cup	03027346938K780752EGSK4
501350	DPA Orig. Green w/ Soft Green Cup	03027346938K780752EGSK4
502814	DenticolorsTM DPA	03027346938K780752EGSK4
502850	DenticolorsTM DPA	03027346938K780752EGSK4
575010	DPA Zooby Assorted Animal Pack	03027346938K780752EGSK4
575050	DPA Zooby Assorted Animal Pack	03027346938K780752EGSK4
120025	Vera By Young™ Soft Petite Web™	03027346938K780752EGSK4
120075	Vera By Young™ Soft Petite Web™	03027346938K780752EGSK4
121025	Vera By Young™ Soft Elite Original™	03027346938K780752EGSK4
121075	Vera By Young™ Soft Elite Original™	03027346938K780752EGSK4
130110	DPA w/ Standard Brush	03027364015Q017332EHKXR
131112	DPA w/ Webbed Cup Gray (Soft)	03027346938K780752EGSK4
131120	DPA w/ Webbed Cup Gray (Soft)	03027346938K780752EGSK4
131312	DPA w/ Webbed Cup White (Firm)	03027346938K780752EGSK4
131320	DPA w/ Webbed Cup White (Firm)	03027346938K780752EGSK4
131420	DPA w/ Webbed Junior™ Cup Gray (Soft)	03027346938K780752EGSK4
131612	DPA BLUE/LTX FR PURPLE/1200 CT	03027346938K780752EGSK4
131620	DPA w/ Latex Free Webbed Cup Purple (Soft)	03027346938K780752EGSK4
131720	DPA w/ Latex Free Webbed Cup Light Blue (Firm)	03027346938K780752EGSK4
132112	DPA w/ Turbo™ Cup Gray (Soft)	03027346938K780752EGSK4
132120	DPA w/ Turbo™ Cup Gray (Soft)	03027346938K780752EGSK4
132312	DPA w/ Turbo™ Cup White (Firm)	03027346938K780752EGSK4
132320	DPA w/ Turbo™ Cup White (Firm)	03027346938K780752EGSK4
134612	DPA w/ Latex Free Petite Web Cup Purple (Soft)	03027346938K780752EGSK4

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134620	DPA w/ Latex Free Petite Web Cup Purple (Soft)	03027346938K780752EGSK4
134712	DPA w/ Latex Free Petite Web Cup Light Blue (Firm)	03027346938K780752EGSK4
134720	DPA w/ Latex Free Petite Web Cup Light Blue (Firm)	03027346938K780752EGSK4
135612	Classic DPA Elite w/ Turbo Plus Purple Cup (Soft)	03027346938K780752EGSK4
135620	Classic DPA Elite w/ Turbo Plus Purple Cup (Soft)	03027346938K780752EGSK4
136812	Classic Pink Angle	03027346938K780752EGSK4
136820	Classic Pink Angle	03027346938K780752EGSK4
137710	Classic DPA w/ Firm Pointed Polisher	03027346938K780752EGSK4
138912	Classic Elite Flex DPA	03027346938K780752EGSK4
138920	Classic Elite Flex DPA	03027346938K780752EGSK4
139012	Classic Elite Extend Flex DPA	03027346938K780752EGSK4
139020	Classic Elite Extend Flex DPA	03027346938K780752EGSK4
153112	Contra DPA w/ Turbo Plus™ Cup Gray (Soft)	03027346938K780752EGSK4
153120	Contra DPA w/ Turbo Plus™ Cup Gray (Soft)	03027346938K780752EGSK4
153312	Contra DPA w/ Turbo Plus™ Cup White (Firm)	03027346938K780752EGSK4
153320	Contra DPA w/ Turbo Plus™ Cup White (Firm)	03027346938K780752EGSK4
153612	DPA CONTRA/PPL LF TP/1200 CT	03027346938K780752EGSK4
153620	DPA CONTRA/PPL LF TP/200 CT	03027346938K780752EGSK4
153712	DPA CONTRA/LT BLUE LF TP/1200	03027346938K780752EGSK4
153720	DPA CONTRA/LT BLUE LF TP/200CT	03027346938K780752EGSK4
154612	Contra DPA w/ Latex Free Petite Web Cup Purple (Soft)	03027346938K780752EGSK4
154620	Contra DPA w/ Latex Free Petite Web Cup Purple (Soft)	03027346938K780752EGSK4
154712	Contra DPA w/ Latex Free Petite Web Cup Light Blue (Firm)	03027346938K780752EGSK4
154720	Contra DPA w/ Latex Free Petite Web Cup Light Blue (Firm)	03027346938K780752EGSK4
155512	Contra Elite Pink Angle	03027346938K780752EGSK4
155520	Contra Elite Pink Angle	03027346938K780752EGSK4
155612	Classic DPA Elite w/ Turbo Plus Purple Cup (Soft)	03027346938K780752EGSK4
155620	Classic DPA Elite w/ Turbo Plus Purple Cup (Soft)	03027346938K780752EGSK4
156812	Contra Elite Flex DPA	03027346938K780752EGSK4
156820	Contra Elite Flex DPA	03027346938K780752EGSK4
157012	Contra Elite Extend Flex DPA	03027346938K780752EGSK4
157020	Contra Elite Extend Flex DPA	03027346938K780752EGSK4
160025	Vera By Young™ Contra Soft Petite Web™	03027346938K780752EGSK4
160075	Vera By Young™ Contra Soft Petite Web™	03027346938K780752EGSK4
161025	Vera By Young™ Contra Soft Elite Original™	03027346938K780752EGSK4
161075	Vera By Young™ Contra Soft Elite Original™	03027346938K780752EGSK4
295696	Sample, DPA, Young Brands, 6ct	03027346938K780752EGSK4
295680	DPA, Young Brands, Elite, Soft, Contra, LF, 125ct	03027346938K780752EGSK4
295681	DPA, Young Brands, Elite, Soft, Classic, LF, 125ct	03027346938K780752EGSK4

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295682	DPA, Young Brands, Petite Web, Soft, Contra, LF, 125ct	03027346938K780752EGSK4
295683	DPA, Young Brands, Petite Web, Soft, Classic, LF, 125ct	03027346938K780752EGSK4
295814	DPA, Young Slim Classic, Purple Petite Web LF, 200ct	03027346938K780752EGSK4
295815	DPA, Young Slim Classic, Purple Petite Web LF, 1200ct	03027346938K780752EGSK4
295816	DPA, Young Slim Classic, Purple Elite LF, 200ct	03027346938K780752EGSK4
295817	DPA, Young Slim Classic, Purple Elite LF, 1200ct	03027346938K780752EGSK4

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