

	Document Number	F1C7002	Revision: E	Effective Date: 07-APR-2021
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<b>Declaration of Conformity</b>				

## ***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**

<b>Legal Manufacturer:</b>	<b>Astek Innovations Ltd</b>
<b>Legal Manufacturer Address:</b>	Astek House, Atlantic Street, Altrincham, WA14 5DH, UK
<b>Technical File Number:</b>	TF-AL-017
<b>Declaration of Conformity Number:</b>	DoC-AL-017
<b>Declaration of Conformity Issue Date:</b>	12 <sup>th</sup> May 2021

We the manufacturer Astek Innovations Ltd, 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.

<b>Product Classification:</b>	Class I
<b>Product Family:</b>	Transform Heat Mouldable Impression Trays
<b>Product Family Intended Use:</b>	Taking impressions where unusual soft tissue, bone shape and tooth position exists
<b>Common Specifications:</b>	<i>Device meets the requirements through harmonized standards, see Technical File</i>
<b>Sterile:</b>	Supplied non sterile
<b>Measuring Function:</b>	N/A
<b>Directive Classification and Rule #</b>	Class I Rule 5 (Appendix 8)

<b>Notified Body (Name and Identification Number):</b>	N/A
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<b>Conformity Assessment Procedure:</b>	
<b>CE Certificate Number:</b>	N/A
<b>EU Representative (Name and Address):</b>	Young Microbrush Ireland Ltd. Clogherane, Dungarvan, Co. Waterford, X35 VE02, Ireland

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**Declaration of Conformity**The undersigned authorized person signing  
for and on behalf of:

Printed Name and Title:

**Paula Hollowood, General Manager**

Signature:

Date:

**12<sup>th</sup> May 2021****Product Family Item Number Listing**

Product Number	Product Description	UDI-DI
118201	Transform Tray - Dentate - Large Lower #1	5060111780692
118202	Transform Tray - Dentate - Large Upper #2	5060111780708
118203	Transform Tray - Dentate - Medium Lower #3	5060111780715
118204	Transform Tray - Dentate - Medium Upper #4	5060111780722
118205	Transform Tray - Dentate - Small Lower #5	5060111780739
118206	Transform Tray - Dentate - Small Upper #6	5060111780746
118207	Transform Tray - Edentulous - Large Lower #7	5060111780753
118208	Transform Tray - Edentulous - Large Upper #8	5060111780760
118209	Transform Tray - Edentulous - Medium Lower #9	5060111780777
118210	Transform Tray - Edentulous - Medium Upper #10	5060111780784
118211	Transform Tray - Edentulous - Small Lower #11	5060111780791
118212	Transform Tray - Edentulous - Small Upper #12	5060111780807
118213	Transform Tray - Edentulous - Mixed Bag 2 x #7-12	5060111780814
118214	Transform Tray - Dentate - Mixed Bag 2 x #1-6	5060111780821
118200	Transform Sample Pack	5060111782344

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