

	DoC Ref:	DoC-101
EU Declaration of Conformity	Version:	10

## EU Declaration of Conformity for Clearwax Earwax Visualisation Devices

### Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

This EU declaration of conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in Regulation (EU) 2017/745, and other applicable Union legislation as listed in Annex 1 to this declaration, have been fulfilled in relation to the devices listed in Annex 3 to this declaration.

<b>Name of Manufacturer or Trade Name:</b>	<b>Clearwax Ltd.</b> 1 Grange Lodge Cottages, Stoughton Grange Rural Centre, Gartree Road, Oadby, Leicester, LE2 2FB, UK
<b>Single Registration Number (SRN):</b>	GB-MF-000010886
<b>Basic UDI-DI:</b>	As per Annex 3 – Device Listing
<b>Product Name:</b>	Clearwax Earwax Visualisation Devices
<b>Product Codes or Catalogue Numbers:</b>	As per Annex 3 – Device Listing
<b>Intended Purpose:</b>	The intended purpose of the earwax visualisation devices is to view the inside of the ear to aid in ear wax removal procedures.
<b>Risk Class:</b>	I
<b>Classification Rule:</b>	As per Annex 3 – Device Listing
<b>Sterile:</b>	No
<b>Measuring Function:</b>	No
<b>Reusable Surgical Instrument:</b>	No
<b>Common Specifications (CS):</b>	As per Annex 2 – Device Listing
<b>Notified Body:</b>	Not applicable for Class I
<b>Conformity Assessment Procedure:</b>	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745
<b>Certificate Type(s) and Reference Number(s):</b>	None
<b>EU Authorised Representative:</b>	Name/Address: <b>Advena Limited</b> Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.  SRN: MT-AR-000000234
<b>Additional Information:</b>	None

	DoC Ref:	DoC-101
<b>EU Declaration of Conformity</b>	Version:	10

**Declaration Signature:**

Date: 24 NOV 2023

Location: As above

Name: Neel Raithatha

Position: Director, Clearwax Ltd.

Who is, or has been delegated the task of ensuring compliance of the devices by, the person responsible for regulatory compliance of the manufacturer.

Signed:  \_\_\_\_\_

**Revision History:**

Version	Compiled By	Date	Description
1.0	Farhaan Shaikh	21 <sup>st</sup> March 2016	First issue
2.0	Kirsty Ostle	10 <sup>th</sup> January 2021	Updated to include EU AR address/new DoC format
3.0	Andrea Thomas	14 <sup>th</sup> July 2021	Update to MDR requirements
4.0	Kirsty Ostle	2 <sup>nd</sup> August 2021	'UK' added to client address. Client SRN number, & EU Authorised Representative's name/address/SRN added
5	Sarah Pavitt	21 SEP 2022	Addition of WAXscope, basic UDI-Dis, product codes and classification rules
6	Sarah Pavitt	22 SEP 2022	Addition of UDI-DI codes in Annex 3
7	Neel Raithatha	01 FEB 2023	Addition of Product Name
8	Bijayata Upadhyay	27 SEP 2023	Addition of new product- Speculum manufactured by Clearwax
9	Neel Raithatha	23 NOV 2023	Addition of EMDN codes
10	Bijayata Upadhyay	24 NOV 2023	Amendment to classification rule

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### ANNEX 1 – Union legislation

The devices listed in Annex 3 are in conformity with the following Union legislation:

- Regulation (EU) 2017/745

### ANNEX 2 – Common Specifications (CS) and applicable standards

There are currently no CS's which apply to these devices.

#### Applicable standards

Standard/Document Name	Description
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – General requirements
EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer

### ANNEX 3 – Device Listing

Product Code	Product Name	Classification Rule	Basic UDI-DI	UDI-DI	EMDN
CS	CLEARscope	5	5065005841CSAS	5065005841008	Z12149006
WS	WAXscope	5	5065005841WSCN	5065005841046	Z12149006
CL	CLEARlite	5	5065005841CLAC	5065005841015	Z12020402
WSS-350	WAXscope Specula (Size 1 = 3.50mm)	5	5065005841WSS6L	5065005841077	Q0399
WSS-425	WAXscope Specula (Size 2 = 4.25mm)	5	5065005841WSS6L	5065005841084	Q0399
WSS-500	WAXscope Specula (Size 3 = 5.00mm)	5	5065005841WSS6L	5065005841091	Q0399
WSS-575	WAXscope Specula (Size 4 = 5.75mm)	5	5065005841WSS6L	5065005841107	Q0399