



By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 613829
Issued To: **Ultimate Wireforms, Inc.**
200 Central St.
Bristol
Connecticut
06010
USA

In respect of:

Design and Development and Manufacture of Orthodontic Wires, Springs and Accessories

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2014-07-04**

Date: **2019-03-05**

Expiry Date: **2023-09-17**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 613829**
 Date: **2019-03-05**
 Issued To: **Ultimate Wireforms, Inc.**
200 Central St.
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Date	Reference Number	Action
04 July 2014	8149768	First issue - transfer from TUV.
14 September 2018	8923023	Certificate renewal. Addition of Emergo Europe for EU Representative. Addition of [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED] as crucial suppliers.
05 March 2019	8149775	Traceable to NB 0086.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
16 March 2023	3854618	Remove previously listed EU representative Addition of new EU representative Addition of subcontractor

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16 March 2023

Ultimate Wireforms, Inc.
200 Central St.
Bristol
Connecticut
06010
USA

To whom it may concern,

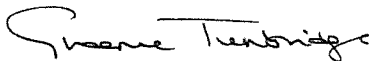
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 613829	93/42/EEC Annex II excluding Section 4	3854618	Remove previously listed EU representative Addition of new EU representative Addition of subcontractor

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices