

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 654572**  
**Issued To:** **UAB "Medicinos linija"**  
**Karaliauciaus str. 29**  
**Siauliai**  
**LT-78348**  
**Lithuania**

In respect of:

**Design and manufacture of dental restorative adhesives, filling materials, temporary cements, etchants, composites, liners, pit and fissure sealants, glass ionomer cements, zinc-based cements, denture and orthodontic resins, acrylic teeth and endodontic solutions**

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: **2016-08-01**

Date: **2019-10-03**

Expiry Date: **2024-05-26**

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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.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Subcontractor:**

**Service(s) supplied**

Advanced Health Care Limited  
Chiddingstone Causeway  
Tonbridge  
Kent  
TN11 8JU  
United Kingdom

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

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 Date: **2019-10-03**  
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**Lithuania**

| Date  | Reference Number | Action   |
|---|------------------|--|
| 01 August 2016  | 8535712          | First Issue.<br>Transfer from another Notified Body.   |
| 25 February 2019  | 8864218          | Traceable to NB 0086   |
| 03 October 2019   | 3045585          | Renewal.<br>Removal of Crucial subcontractor: JSC Experimental Plant VladMiVa  |
| <b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b> |                  |  |
| 18 October 2021   | 3373322          | Change of legal manufacturer address to Aviacijos st.28, Siauliai, LT-77103, Lithuania.<br>Removal of denture and orthodontic resins, acrylic teeth from scope.<br>Remove subcontractors Dental Manufacturing SpA and Vertex-Dental B.V. |

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18 October 2021

UAB "Medicinos linija"  
 Aviacijos st.28  
 Siauliai  
 LT-77103  
 Lithuania

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 26<sup>th</sup> 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 654572   | 93/42/EEC Annex II excluding Section 4 | 3373322          | <p>Change in legal manufacturer address from "Karaliaucius str. 29 Siauliai, LT-78348, Lithuania" to "Aviacijos st.28, Siauliai, LT-77103, Lithuania"</p> <p>Scope reduced from "Design and manufacture of dental restorative adhesives, filling materials, temporary cements, etchants, composites, liners, pit and fissure sealants, glass ionomer cements, zinc-based cements, denture and orthodontic resins, acrylic teeth and endodontic solutions" to "Design and manufacture of dental restorative adhesives, filling materials, temporary cements, etchants, composites, liners, pit and fissure sealants, glass ionomer cements, zinc-based cements and endodontic solutions"</p> <p>Removal of subcontractors Dental Manufacturing SpA and Vertex-Dental B.V.</p> |

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,



Gary Slack  
 Senior Vice President, Medical Devices

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