

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 534469****Issued To:**

**CDB Corporation
9201 Industrial Boulevard NE
Leland
North Carolina
28451
USA**

In respect of:

The manufacture of composite, ceramic and metal orthodontic brackets and accessories

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2008-04-21**

Date: **2019-03-01**

Expiry Date: **2023-04-20**

...making excellence a habit.™

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.

12th June 2024

CDB Corporation
8770 Trade Street, Suite A, Leland
North Carolina, 28451
USA

To whom it may concern,

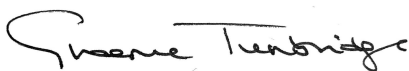
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 534469	93/42/EEC Annex V	30164197	Change in legal manufacturer address from "CDB Corporation, 9201 Industrial Boulevard NE, North Carolina, 28451 USA" to "CDB Corporation, 8770 Trade Street, Suite A, Leland, North Carolina, 28451, USA".

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