BSI Migration of Certificates from UK Notified Body (0086) to NL Notified Body (2797)

BSI operates two full scope Notified Bodies, which cover all NBOG codes for the Medical Device Directives (MDD, AIMD, and IVDD):

United Kingdom	**Netherlands**
Notified Body Number 0086	**Notified body number 2797**
BSI Kitemark Court Davy Avenue Milton Keynes MK5 8PP	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam

Please Note: This letter provides validation only where BSI NB 2797 certificate(s) accompany the document.

The named manufacturer has completed migration of the enclosed CE certificate(s), originally issued by BSI UK (0086) Notified Body to BSI Group The Netherlands B.V. which is a European Notified Body designated in The Netherlands for the following three directives: MDD (93/42/EEC), AIMDD (90/385/EEC) and IVDD (98/79/EC).

The migrated certificates retain their original certificate references to ensure traceability and to maintain full visibility of the significant history of the previous certification changes for the product or product family concerned. BSI Group The Netherlands B.V will maintain and continue with the full surveillance audit schedule set previously by BSI UK. The maintained traceability ensures all regulatory requirements under the Directives remain valid and assessed on an ongoing basis and manufacturers do not need to update their labelling immediately.

Your Sincerely

Gary Slack

SVP Notified Body and Brexit Strategist,

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 635656**

Issued To: **FlexMedics**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

In respect of:

Manufacture of Elastomers, Non-latex Intraoral Elastics, Hooks, Elastic Bands, Orthodontic Wires, Orthodontic Springs, Orthodontic Expanders, Ligature Wires, Expansion Screws, Orthodontic Bands, Orthodontic Tubes and Orthodontic Brackets

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):

Albert Roossien, Regulatory Lead

First Issued: **2015-10-09** Date: **2019-02-08** Expiry Date: **2022-10-03**

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