

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,

...making excellence a habit™