To the attention of Designated Auditing Organization

2017-01-23

Dear Sir

This letter is promulgated under the Technical Cooperation Program between UL International (UK) Ltd and the Designated Auditing Organizations of Chinese-Taipei.

We declare that the Quality Management System of:

HumanTech Germany GmbH
Gewerbestrasse 5
71144 Steinenbronn
Germany

has been assessed by UL International (UK) Ltd to the requirements of standard ISO 13485:2003 – Medical Devices Quality Management System – Requirements for Regulatory Purposes and is in possession of a valid certificate 11127725.20160112 issued by UL International (UK) Ltd on 2016-01-12 and is valid and accurate on the date of this letter.

Furthermore, we hereby confirm that currently, the following medical devices are covered by the scope of the certified quality management system:

Cervical Plate-Screw Fixation System	(class IIb);
Spinal Screw Rod Fixation System	(class IIa and IIb);
Anterior Cervical Interbody Devices	(class IIa and IIb);
Lumbar Interbody Devices	(class IIb);
Dental Implants	(class IIb)
Cement Applicator	(class IIa);
Cover Screws	(class IIa);
Dental Instruments	(class IIa);
Abutments	(class IIb)
Vertebral Body Replacement	(class IIb)

The most recent assessment of the Quality Management System by UL International (UK) Ltd occurred on 2016-12-22 and all action requests raised during that assessment have been satisfactorily addressed. The manufacturer listed above continues to be in conformance with the aforementioned standard. As a record of this assessment, an audit report dated 2016-12-23 was issued by UL International (UK) Ltd is appended to this letter. Subsequent to the audit report the manufacturer has made a satisfactory response to address the action requested stated in the report.

Please do not hesitate to contact the undersigned should you have any questions.

Yours faithfully

P. Daysh

Paul Daysh
Head of Medical Notified Body
UL International (UK) Ltd