



Lloyd's Register  
LRQA

[www.lrqausa.com](http://www.lrqausa.com)  
management-usa@lrqa.com  
T +1 281-398-7370  
T +1 888-877-8001  
F +1 281-398-7337

**LRQA**  
Lloyd's Register Quality Assurance, Inc.  
1330 Enclave Parkway, Suite 200  
Houston, TX 77077  
United States

7<sup>th</sup> September 2018

LRQA Reference Number: UQA 00000657

To: Whom it May Concern

This letter is to confirm that LRQA has completed an on-site assessment in accordance with the following criteria during Aug 27-31, 2018:

- Certificate renewal in accordance with ISO 13485:2003 and MDD 93/42/EEC
- Transition to ISO 13485:2016
- Initial / Stage 2 assessment in accordance with Medical Device Single Audit Program [MDSAP].

Notably these assessments have not identified any major non-conformance, therefore the assessors have recommended for certification in accordance with the aforementioned criteria. Upon completion of administrative report writing, as per LRQA process, the audit report will be subject to technical review and subsequently certificates will be issued in due course of time.

If there are any questions of compliance during this process, please do not hesitate to contact LRQA using the contact information listed below.

Yours sincerely,

Salman T. Raza  
Senior Lead Assessor – Medical Devices  
Lloyds Register Quality Assurance Limited  
[Salman.Raza@LRQA.com](mailto:Salman.Raza@LRQA.com)

**Improving performance, reducing risk**