

## **1.2 Quality management system**

We have established and operated quality management system according to ISO13485:2003 Medical devices—Quality management systems — Requirements for regulatory purposes.(Quality manual: Q/ATL-QM-1 version A/0).All the files related to Quality system including quality manual, program, and records are stored in the relative department of our company.

## **1.3 European Authorized Representative**

We hereby authorize M/s Empireum as our European Authorized Representative

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## **Annex 1 European Authorized Representative agreement**