

{On Company Letterhead}

{Sample} **Declaration of Conformity**

I hereby declare that the Products listed on this schedule meet the relevant Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC.

We have Classified our Device(s) as Class I under **Rule(s) # ? (and # ?)** and we have compiled a Technical File in accordance with Annex VII of the Directive. We have registered our Devices with the UK Competent Authority through our Authorized Representative, Medical Device QA Services, 76, Stockport Road, Timperley, Cheshire. WA15 7SN. UK

Product Schedule

{Product # 1, catalogue #} {Description # 1}

{Product # 2, catalogue #} {Description # 2}

{Product # n., catalogue #} {Description #.n}

I further declare that we are implementing documented procedures covering the following;

- 1• Notification to the Competent Authority, of additions or changes to this Product Schedule, through our Authorized Representative.
- 2• Effective handling of Customer Complaints.
- 3• A Post Market Feedback system, to proactively gather information about our products, in the Post Sales Phase.