Declaration of Conformity

for
daysy and daysyView

We hereby declare that the distributed CE marked products, daysy version 1.0 and daysyView version 1.0, are in accordance with Annex II of the "EC-Directive", the Council Directive 92/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class I, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, production, distribution and service of temperature based fertility monitors, in accordance with Annex II of the EC-Directive.

This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:2012, Quality System Certificate with reference number MD 608806 and delivered by BSI Group Deutschland GmbH.

This Declaration of Conformity covers the products daysy and daysyView, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

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