



Declaration of Conformity

According to the In vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer:

Sensitest

Distributieweg 54

2645 EJ Delfgauw

The Netherlands

Medical Device:

Product Name

Sensitest® Ovulation test

Sensitest® Ovulatietest

IVD-Classification

Self-testing device according to IVDD

Sensitest Ovulation test dipstick (se-Ihdip) Sensitest Ovulation test dipstick (se-Ihdip-s) Sensitest Ovulation test dipstick pro (se-Ihdip-pro)

Sensitest Ovulation test dipstick bas (se-Ihdip-bas)

Product Type

Sensitest Ovulation test midstream (se-Ihmid) Sensitest Ovulation test midstream (se-lhmid-s) Sensitest Ovulation test midstream pro (se-lhmid-pro)

Sensitest Ovulation test midstream bas (se-lhmid-bas)

Sensitest Ovulation test cassette (se-Ihcas)

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex I of the European in vitro Medical Device Directive 98/79/EC (IVD).

This declaration of conformity is based on the European In vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.

General Manager Robert Das

SENSITEST

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