

EC DECLARATION OF CONFORMITY IVDD		
Document No.	Document title	Version No.
DOC-2100	EC Declaration of Conformity Miris HMA	1

We, Miris AB, Danmarksgatan 26, SE-753 23 Uppsala, Sweden, hereby declare under our own responsibility that the following product:

Miris Human Milk Analyzer (HMA), article no 08-02-102

meets the provisions of the Council Directive 98/79/EC and the essential requirements which apply.

The above mentioned device has been classified as an *in vitro* diagnostic medical device, product class general, according to Article 1(1), Article 1(2)(b), and Article 9(1) of Council Directive 98/79/EC.

This declaration is based on the conformity assessment of the product to the requirements of Annex III of Council Directive 98/79/EC.

We declare under our own responsibility that the listed products in this declaration are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled Manufacturer.

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Camilla Sandberg, CEO

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