

ORIGINAL DOCUMENT
01 SEP. 2016
- QUALITY CONTROL -

DECLARATION OF CONFORMITY

1) **Manufacturer:** Agendia NV

Address: Sciencepark 406
1098 XH Amsterdam, The Netherlands

2) **Product:** (name, type or model/batch number, etc.)

<u>Product</u>	<u>Version</u>
MammaPrint Fresh	EU011
MammaPrint FFPE	EU03.1

3) **Classification:** Self-declared

4) **The product described above is in conformity with:**

<u>Directive</u>	<u>Title</u>	<u>Edition / Date of issue</u>
98/79/EC	In Vitro Diagnostic Directive (IVDD)	1998-10-27

5) **Additional information:** (conformity procedure, Notified Body, CE certificate, etc.)

Conformity with Annex I and III of the IVDD, ISO13485:2003

6) **GMDN code:** 60943

7) **Date of first CE marking:** 2005-05 (MammaPrint EU01)

01-September-2016

(Date of Issue)



Mark R. Straley, CEO, Agendia NV

(name, function, and signature of manufacturer)



Declaration of Conformity in accordance with EN ISO/IEC 17050-1:2010

Agendia NV • Science Park 406 • 1098 XH Amsterdam • The Netherlands
phone +31 20 4621500 • fax +31 20 4621505 • info@agendia.com • www.agendia.com

ABN AMRO Bank Acc. No.: 44.03.56.628 • IBAN: NL47 ABNA 0440 3566 28 • SWIFT/BIC: ABNA NL 2A
Chamber of Commerce Amsterdam No. 34185452 • VAT No. NL 8125.15.080.B01