

Declaration of Conformity INFLUENCE 2.0 Calculator



Doc ID: 2238-DOC-A5

The manufacturer:



Business name: Evidencio B.V.

Address: Irenesingel 19, 7481 GJ Haaksbergen

Country: The Netherlands

Declares under sole responsibility that the Class I device:

Device name: The INFLUENCE 2.0 Calculator


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INFLUENCE 2.0: Risk of Locoregional recurrence, secondary contralateral tumors and distant metastasis in breast cancer

INFLUENCE 2.0 is a flexible model to predict time-dependent individual risks of LRR, SP and DM at a 5-year scale; it can support clinical decision-making regarding personalized follow-up strategies for curatively treated non-metastatic breast cancer patients.

Research authors: Vinzenz Völkel, Tom A. Huetling, Teresa Draeger, Marissa C. van Maaren, Luc J.A. Strobbe, Marjanka K. Schmidt, Gabe S. Sonke, Marjan van Hezewijk, Catharina G.M. Groothuis-Oudshoorn, Sabine Siesling

Oncology | R-Script model ★★

LOT V-2.0-2238.21.05.14 

Locoregional recurrence
Would you like to display the risk for locoregional recurrence? See results below

Second primary
Would you like to display the risk for second primary tumor?

Metastasis
Would you like to display the risk for metastasis?

Age
Age at the time of surgery 60 years
18 100

Grade

Tumor stage
Pathologic tumor stage

Nodal stage
Pathologic nodal stage

Multifocality

HER2 status

Hormone receptor status ⓘ
Hormone Receptor (HR) status is defined with Estrogen Receptor (ER) & Progesterone Receptor (PR) status as follows:
• ER negative & PR negative = HR negative
• ...

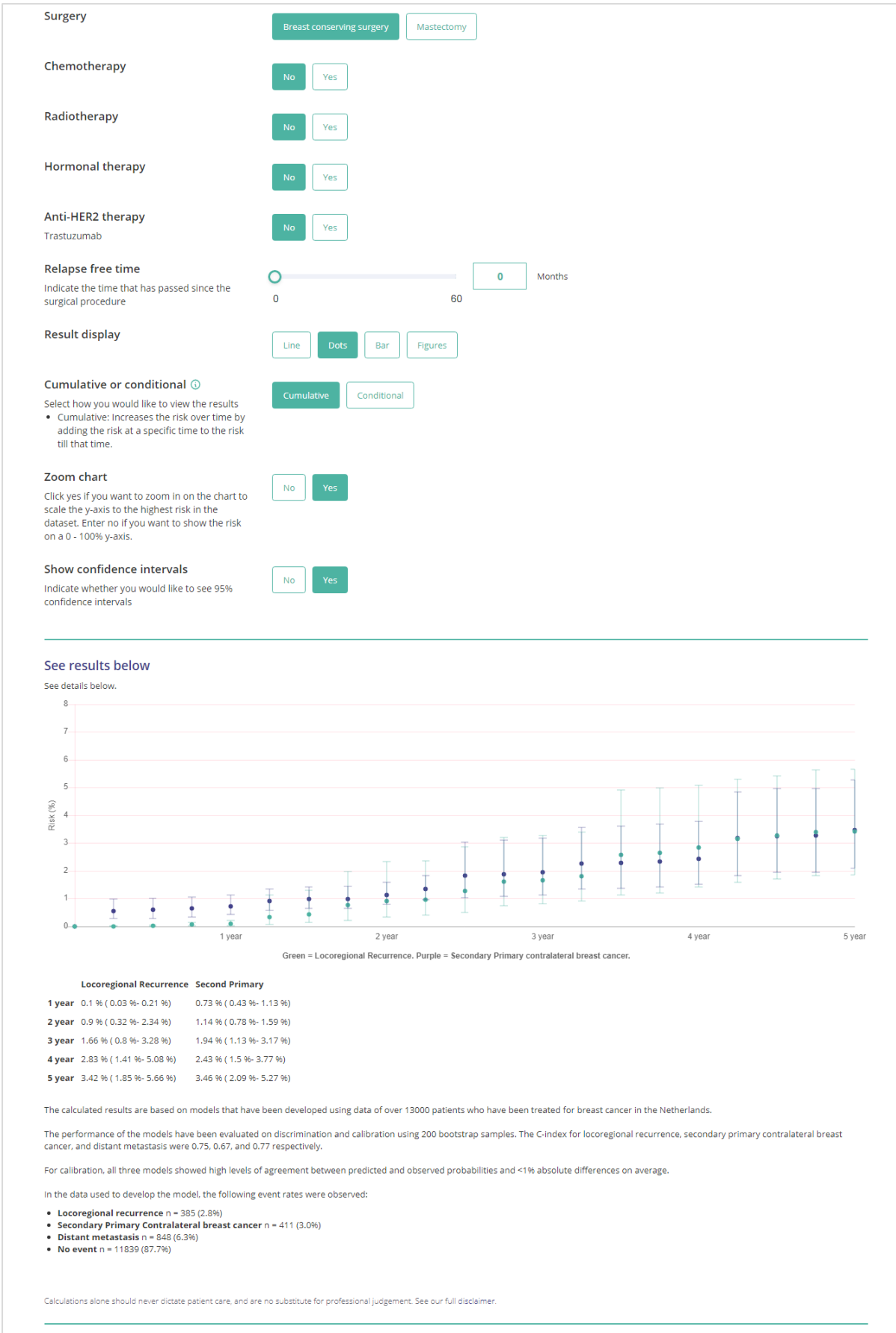


Figure 1 The INFLUENCE 2.0 Calculator.

to which this declaration relates, is in conformity with the essential requirements and other relevant requirements of Directive 93/42/EEC and its Annex VII on medical devices.

Place and date of issue (of this Doc):
Haaksbergen 14 May 2021

Signed by the manufacturer:

A handwritten signature in black ink, appearing to be 'R.J. Mentink', written over a faint circular stamp or watermark.

Dr. ir. R.J. Mentink
Chief Executive Officer
Evidencio B.V.