

REGULATION (EU) 2017/745 (Annex IX)

Quality Management System Certificate

Manufacturer **Health Triage S.p.A.**
Viale della liberazione 111
80125 Napoli
Italy
SRN: IT-MF-000030843

Certificate Number **SCAR-18.2.1.0**

Validity
Issued: **2026-04-30**
Revised: **N/A**
Expiry: **2030-07-24**

Device Range
Risk Classification: **Class IIb**
Device Group: **Z110602 - Digital Computed Radiography Systems**
MDA Code: **MDA 0315**

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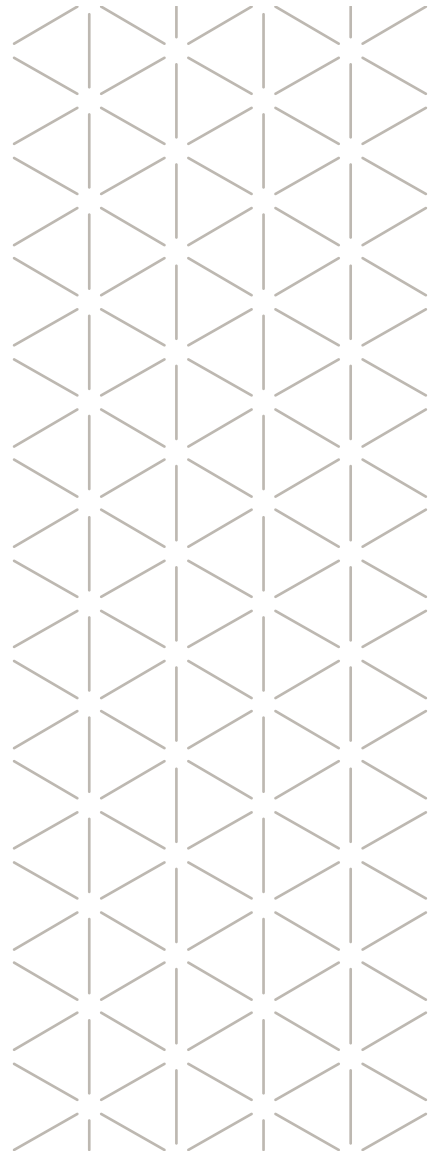
Conditions and Limitations
None

Conformity Assessment Procedure
The relevant conformity assessment procedure according to Regulation (EU) 2017/745, Article 52, which includes:

- conformity assessment as specified in Regulation (EU) 2017/745, Annex IX, Chapters I and III; including
- an assessment of the technical documentation (as specified in Regulation (EU) 2017/745, Annex IX, Section 4) of one representative device.

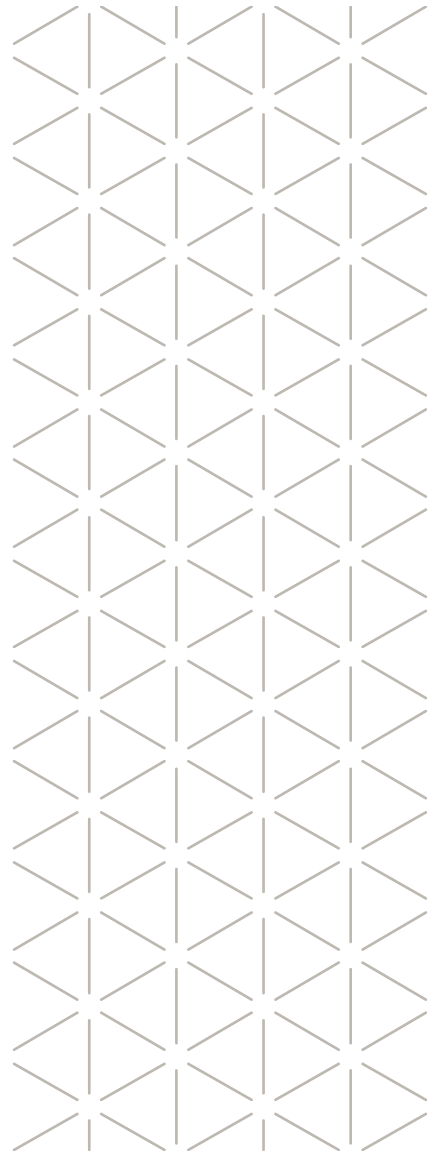
Conformity Assessment Conclusion
For the specified Device Range, Health Triage S.p.A., has successfully demonstrated compliance according to the Conformity Assessment Procedure specified above.

This conclusion is subject to periodic surveillance, pursuant to Regulation (EU) 2017/745, Annex IX, Chapter I, Section 3.



Device Range

Device Range	Device Details	Intended Purpose
Class IIb - Z110602 - Digital Computed Radiography Systems	<p>Name: Breast.ai</p> <p>Basic UDI-DI: 805363611breast01ME</p> <p>Risk Class: IIb</p>	<p>The Breast.ai software medical device, based on Artificial Intelligence models, is intended for use by medical personnel, specifically radiologists specialising in breast imaging, to support the diagnosis of breast cancer.</p> <p>This medical device takes a complete mammogram as input and, by analysing the radiological images, is able to provide a negative output that categorises the outcome of the examination into three different classes:</p> <ul style="list-style-type: none"> • Negative: the examination analysed shows no signs of breast cancer • Double reading needed: the device cannot determine whether a tumour is present or absent • Not processable, the device was unable to process the examination <p>In a double-blind mammography screening context, the 'negative' output aims to eliminate one of the two readings by breast specialists. In the case of a 'Double reading needed' output, the examination is referred back to normal clinical practice.</p> <p>More detail in Annex A.</p>



Certificate Version Control

SCAR-18.2.1.0

Issued: 2026-04-30

Comments: Transferred certificate from IMQ S.p.A.

Audit Report Reference

EUQREP-18.2.1.0

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James Dewar, Director
on behalf of **Scarlet NB B.V.**

NB Number: **3022**

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Annex A

Device: Breast.ai

Indication	The software is indicated to support the diagnosis of breast cancer.
Use environment	Breast.ai is designed for use in a controlled environment. Access to the application is restricted to trained users within the hospital network.
Contraindication	No contraindications. The device is not used directly on the patient.
Users	The software should not be used by personnel other than radiologists specialising in breast imaging.
Patients	<p>There is no target patient group, as the SW is intended for digital image processing. The software is intended for populations undergoing mammographic screening for breast cancer; this choice was made because the software will be used in mammographic screening.</p> <p>However, symptomatic women, women with breast implants or women who have undergone mastectomy are excluded. Mammograms consisting of more than 4 images due to the size of the breast, mammograms of pregnant women and male subjects are also excluded.</p>

