

Number: 2273383CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter I and III

Manufacturer:

Hartwig Medical Foundation

Science Park 408
1098XH Amsterdam
The Netherlands
SRN ID.: NL-MF-000035835

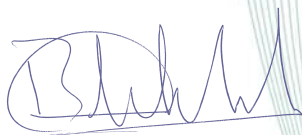
DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2276101CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/746, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/746.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



F. Godeke
Principal Certification Manager

First Issued: 25 June 2026

Date: 25 June 2026

Expiry date: 1 June 2031

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

General purpose IVD Instruments (W0207, Class C)
In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS) (IVP3011)

Device Name: OncoAct

Intended Purpose: OncoAct is an in vitro diagnostic (IVD) medical device consisting of software that analyses whole genome sequencing data for cancer diagnostics and treatment decision making purposes. It detects and measures all types of oncology related DNA-based genomic events and genomic characteristics (biomarkers) that can be relevant for diagnosis and treatment decision making of cancer patients using whole genome DNA sequencing data derived from non-formalin fixated tumor and reference biomaterial. Analytical results can be quantitative as well as qualitative. The product of the software that is delivered to the customer involves a report that presents an overview of oncology related genomic events and characteristics (biomarkers) including links to associated treatments and possible clinical studies. OncoAct is only made available to registered clinicians or other registered medical experts who have requested the IVD test, to facilitate and/or support diagnosis and treatment decision making for cancer patients. The intended clinical use of OncoAct are cancer patients that seek systemic treatment and for whom the biomaterials, tumor material with sufficient tumor cells and a reference sample, can be collected safely.

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	25 June 2026	2276101CN01	first issue

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