OncoAct EU declaration of conformity

HMF-IVDD-280 **V**1.0

Hartwig Medical Foundation hereby declares that the product specified below meet the relevant provisions of the European In Vitro Diagnostic Medical Device Regulation IVDR 2017/746. This declaration is based on conformity of:

a) the Quality Management System (ATT-281 ISO13485 cross reference table)
b) the product Hartwig Medical OncoAct (IVDD-241 OncoAct Requirements)

Trade name	Device name	Version	(Basic) UDI-DI	SRN
Hartwig Medical	OncoAct	V5.33-1.0	87202994860ONA8120058J8	NL-MF-000035835

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.

The conformity assessment procedure is followed in accordance with Annex IX of the Regulations. The certificates (table below) as issued by DEKRA Certification B.V. NB 0344.

Certificate	Scope	Classification	Certificate no.	Valid until
EU quality management system certificate	OncoAct	C	2273383CE01	31 May 2031

An application for the concerned product is not submitted to any other Notified Body than mentioned in this Declaration of Conformity.

Person Responsible for Regulatory Compliance:	Place of issue EU declaration of conformity, and company address:	Issue and sign date:	Signed by:	Signature
Desiree van der Kleij Diagnostic Services Lead (PRRC)	Hartwig Medical Foundation Science Park 408 1098 XH Amsterdam Netherlands	30/06/2026 14:46	Desiree van der Kleij	

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.