EU Certificate

for the assessment of the quality management system

according to Regulation on In-vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter I+III

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

ZytoVision GmbH

Single Registration Number (SRN): DE-MF-000024390
Fischkai 1, 27572 Bremerhaven, Germany

applies a quality management system according to Annex IX Chapter I+III of the regulation on in-vitro diagnostic medical devices (EU) 2017/746 for the devices listed in the annex. This certificate is based on the assessments listed in CNo51552-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51552-70-00-00

Certificate valid from: 2024-05-10
Certificate valid to: 2028-01-15

Digitally signed by CORD JOHANNES WIORA
Date: 2024-05-21 06:16:33+02:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-100

DEKRA Certification GmbH, Stuttgart
Notified Body ID: 0124

Annex to the EU Certificate no. 51552-70-00-00

Following devices/device categories are included in this certificate:

Classification:	Class C
Device Group:	W010307 - HISTOLOGY / CYTOLOGY REAGENTS
IVP Code:	IVP 3010 - In vitro diagnostic devices which require knowledge regarding microscopy
Intended Purpose:	IVR 0302 - Markers of cancer and non-malignant tumors

Change to previous certificate: n.a.