BEMARA
Bemarituzumab in patients with FGFR2b-positive advanced or metastatic adenocarcinoma of the stomach or gastroesophageal junction, who failed at least one prior line of palliative chemotherapy - The IKF-AIO-BEMARA Phase IIa trial

EU CT number: 2024-512484-31-00
Sponsor's Protocol Code: BEMARA

Public declaration regarding the manufacture and use of in-house devices by health institutions (in accordance with Annex A of MDCG 2023-01)

Name of health institution: Institut für Pathologie der Universitätsmedizin der Johannes Gutenberg-Universität Mainz

Address: Langenbeckstraße 1
55131 Mainz

We, the Institut für Pathologie der Universitätsmedizin der Johannes Gutenberg-Universität Mainz as Central Pathology in the above mentioned trial, declare that the devices described in the accompanying table will only be manufactured and used within the Institut für Pathologie der Universitätsmedizin der Johannes Gutenberg-Universität Mainz and will meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745) or of the *in vitro* diagnostic medical devices Regulation (EU 2017/746). A reasoned justification would be provided in case applicable general safety and performance requirements were not fully met.

INSTITUT FÜR PATHOLOGIE
DER UNIVERSITÄTSMEDIZIN MAINZ
Langenbeckstr. 1 - 55131 Mainz

Mainz, 16.8.24
Ort, Datum

Univ.-Prof. Dr. med. Wilfried Roth
Direktor Institut für Pathologie

Mainz, 16.08.24
Ort, Datum

PD Dr. med. Daniel-Christoph Wagner
Facharzt für Pathologie, Leiter zentrale Testung in der BEMARA Studie

Table of in-house devices:

Device identification (e.g. name, description, reference number)	Device type (IVD/MD)	Risk class of the device	Intended purpose	Applicable GSPR will be fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)
FGFR2b IHC testing using VENTANA FGFR2b mouse monoclonal antibody	*IVD*	*Class C*	*Assess the FGFR2b expression status of patients with advanced or metastatic adenocarcinoma of the stomach or gastroesophageal junction, who failed at least one prior line of palliative chemotherapy, for a subsequent therapy with an FGFR2b inhibitor (bemarituzumab)*	*Yes*	*n.a.*