Manufacturers Name:	MetaSystems Hard & Software GmbH
Manufacturers Address:	Robert-Bosch-Str. 6 68804 Altlussheim Germany
SRN (Single Registration Number):	DE-MF-000016548
Basic UDI-DI:	42504064METAFERF5
Name of the Device (s):	Metafer 4.3
Intended purpose	As per attached appendix
Classification:	Class A
Conformity assessment procedure:	MetaSystems Hard & Software GmbH uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746: Class A EC conformity assessment according to Article 48 and Annex II and III

This declaration of conformity is issued under the sole responsibility of MetaSystems Hard & Software GmbH. We hereby declare that the in vitro diagnostic medical device Metafer 4.3 meet the provision of the Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices.

Signature:

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Dr. Andreas Pfuhl
Managing Director

Place and date of issue:

Altlussheim, 25.05.2022

Appendix to declaration of conformity

Intended Purpose:

Metafer is a software intended to control microscope and accessory hardware, to acquire digital images, and to assist the operator in the detection, classification, and counting of cells of human or other origin and other objects in microscopic specimen.
Metafer is intended for use in *in vitro* diagnostic procedures by clinical and non-clinical laboratories in accordance with their established procedures. Slide scanning and analysis conditions can be adapted to a variety of specimen, including, but not limited to, cultured and stained cells in their interphase or metaphase state. The analytical and clinical performance has not been established.