

Declaration of Conformity

The following in-vitro diagnostic medical devices

Name of product: **Metafer**

Release Version: 3.13

fulfill the applicable requirements of the directive 98/79 EC of 27 Oct. 1998, "Other (General)".

This declaration covers all options and configurations of the above products delivered by MetaSystems

Manufacturer: **MetaSystems Hard & Software GmbH**

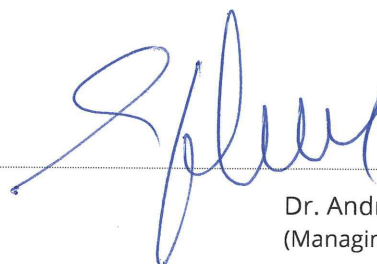
Address: Robert-Bosch-Strasse 6
D-68804 Altlussheim, Germany

The MetaSystems products are in-vitro diagnostic medical devices according to

GMDN CT1250 Analyser software IVDs

This declaration of conformity is issued under the responsibility of MetaSystems Hard & Software GmbH.
The appendix is part of this declaration of conformity.

Altlussheim, 2018-06-27



Dr. Andreas Plesch
(Managing Director)

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Appendix of Declaration of Conformity (Metafer 3.13)

MetaSystems products consist of software modules, hardware components and accessories in different configurations.

The entire system subject to this declaration consisting of specified, verified and validated hardware components, software modules and their accessories after commissioning by system specialists or commissioned third parties.

Only components, modules and accessories specified, verified and validated by MetaSystems can be replaced by MetaSystems specialists or commissioned third parties as part of maintenance or servicing.

This Declaration of Conformity is valid for all variations of the following MetaSystems products.

Reference No.	Description
P-2000-001-MS	Automated Metaphase Finder System Metafer – MSearch
P-2000-002-MS	MSearch upgrade for Metafer (additional application)
P-2010-001-MS	Automated Scanning System Metafer - MetaCyte
P-2010-002-MS	MetaCyte upgrade for Metafer (additional application)
P-2010-003-MS	MetaCyte Lite
P-2010-004-MS	MetaCyte Lite system upgrade to full MetaCyte scanning system
P-2015-001-MS	CometScan upgrade for Metafer - MSearch (additional application)
P-2015-002-MS	Automated Scanning System Metafer – CometScan
P-2020-001-MS	Automated Scanning System Metafer - RCDetect
P-2020-002-MS	RCDetect upgrade for Metafer (additional application)
P-2025-001-MS	Virtual Slide Scanner Metafer - VSlide
P-2025-002-MS	VSlide Upgrade for Metafer (additional application)

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Reference No.	Description
P-2050-007-MS	Metafer Analysis Station (w/o monitor)
P-2050-008-MS	Metafer Review Station (w/o monitor)
P-2060-001-MS	Relocation System Relosys (without Camera)
P-2060-005-MS	Relosys Review Software
P-2060-011-MS	Relocation System Relosys with CoolCube 1m
P-2070-002-MS	DCScore upgrade for Metafer MSearch
P-2070-003-MS	MNScore upgrade for Metafer - MSearch
P-2070-004-MS	AutoCapt upgrade for Metafer - MSearch or RCDetect
P-2070-005-MS	CometScan upgrade for Metafer - MetaCyte
P-2070-008-MS	MetaCyte PV upgrade
P-2070-010-MS	Metafer analysis upgrade for Isis
P-2070-011-MS	TissueFISH Module for MetaCyte-Analysis or MetaCyte Lite
P-2070-018-MS	MNScoreX Upgrade for Metafer – MSearch
P-2070-019-MS	MNScoreX Upgarde for MNScore
P-7500-004-MS	Automated Scanning System Metafer – Gram Scanner
P-7500-005-MS	MycobacteriaDetect Module for Metafer
P-7500-007-MS	Automated Scanning System Metafer – Mycobacteria Scanner

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The system can include hardware components as follows:

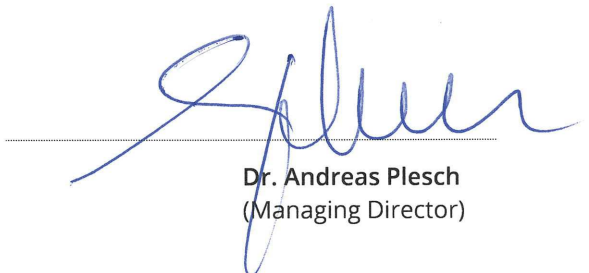
P-2070-020-MS	Metafer CoolCube1m Camera Package
P-2070-021-MS	Metafer CoolCube1c Camera Package
P-2070-024-MS	Metafer CoolCube4m Camera Package
P-2070-025-MS	Metafer CoolCube4c Camera Package
P-2070-026-MS	Metafer CoolCube4m TEC Camera Package
P-2070-027-MS	Metafer CoolCube4c TEC Camera Package
C-0005-012-DE	24" Monitor [1920x1200] for analysis or review systems
C-0005-015-DE	30" Monitor [2560x1600] for analysis or review systems

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Accessories	
P-2070-006-MS	Barcode Software upgrade for Metafer
P-2070-013-MS	Metafer Remote Review Upgrade
P-2070-001-MS	Security package upgrade for Metafer
P-2070-007-MS	Security package upgrade for Relosys, Metafer Analysis and Metafer Review
P-6000-003-MS	Automated SlideFeeder x80 for Metafer
P-6010-004-MS	AutoOiler Module for Axiolmager
P-6010-012-MS	BarCodeReader Module for SlideFeeder x80

This addendum is only valid if attached to the certificate mentioned above.

Altlussheim, 2018-08-21



Dr. Andreas Plesch
(Managing Director)

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