

EU-Declaration of Conformity

Manufacturer	Chromsystems Instruments & Chemicals GmbH
Address	Am Haag 12 82166 Gräfelfing, Germany
SRN (single registration number)	DE-MF-000010089

Assay MassTox® Drugs of Abuse Testing (ID 96096)		
Order No.	Device Description	EMDN Code
Basic UDI-DI: 4250317960006Z		
96096-BK	LC-MS/MS Basic Kit MassTox® Drugs of Abuse Testing in urine	W01010499
96096-A-BK	LC-MS/MS Basic Kit MassTox® Drugs of Abuse Testing in urine with 96 Deep Well Plates	W01010499
96038	6PLUS1® Multilevel Urine Calibrator Set	W0101050301
4410	MassCheck® Drugs of Abuse Testing Urine Control Set Level I	W0101050207
4420	MassCheck® Drugs of Abuse Testing Urine Control Set Level II	W0101050207
4430	MassCheck® Drugs of Abuse Testing Urine Control Set Level III	W0101050207
4480	MassCheck® Drugs of Abuse Testing Urine Hydrolysis Control Set	W0101050207
4490	Hydrolysis Reference	W0101050207
96009	Rinsing Solution	W01019099
96011	Hydrolysis Buffer 2	W01019099
96015	Tuning Mix 1	W0101050399
96016	Tuning Mix 2	W0101050399
96017	Tuning Mix 3	W0101050399
96019	Dilution Reagent	W01019099
96020	Spike Solution	W0101050399
96021	Mobile Phase A	W01019099
96022	Mobile Phase B	W01019099
96055	Precipitation Reagent	W01019099
96054	96 Deep Well Plates	W01019099
96059	Pierceable Adhesive Seals	W01019099
96061	Pierceable Heat Seals	W01019099
96100	Analytical Column	W01019099
96446	Internal Standard Set	W0101050399
96778	Enzyme Solution Set	W01019099

Device Intended Purpose	The Chromsystems assay " MassTox® Drugs of Abuse Testing" is an in-vitro diagnostic medical device intended for professional users in clinical laboratories and is used for quantitative determination of the below listed substances in human urine:				
	Amphetamine	Demoxepam	Cocaethylene	Oxymorphone	
	BDB	Desalkylflurazepam	Cocaine	Papaverine	
	Butylone	Desmethyflunitrazepam	Norcocaine	Propoxyphene	
	2C-B	Diazepam	11-Nor-9-carboxy-Δ9-THC	Sufentanil	
	2C-I	Estazolam	Acetylcodeine	Tapentadol	
	Cathinone	Flunitrazepam	Buprenorphine	Thebaine	
	MBDB	Flurazepam	Codeine	Tilidine	
	MDA	α-Hydroxyalprazolam	Dihydrocodeine	Tramadol	
	MDEA	α-Hydroxymidazolam	EDDP	Zaleplon	
	MDMA	α-Hydroxytriazolam	Fentanyl	Zolpidem	
	MDPV	3-Hydroxybromazepam	Hydrocodone	Zopiclone	
	Mephedrone	Lorazepam	Hydromorphone	Ketamine	
	Methamphetamine	Lormetazepam	Meconin	LSD	
	Methaqualone	Medazepam	Meperidine	Mescaline	
	Methylone	Midazolam	Methadone	Norketamine	
	Methylphenidate	Nitrazepam	6-Monoacetylmorphine	2-Oxo-3-hydroxy-LSD	
	PMA	Norclobazam	Morphine	PCP	
	Ritalinic Acid	Nordiazepam	Naloxone	Allobarbitol	
	Alprazolam	Oxazepam	Naltrexone	Amobarbital	
	7-Aminoclonazepam	Praxepam	Norbuprenorphine	Barbital	
	7-Aminoflunitrazepam	Temazepam	Norcodeine	Butalbital	
	7-Aminonitrazepam	Triazolam	Norfentanyl	Hexobarbital	
	Bromazepam	Gabapentin	Normeperidine	Pentobarbital	
	Brotizolam	Pregabalin	Nortapentadol	Phenobarbital	
	Chlordiazepoxide	Promethazine	Nortilidine	Secbutobarbital	
	Clobazam	Quetiapine	O-Desmethyltramadol	Secobarbital	
	Clonazepam	Benzoyllecgonine	Oxycodone	Thiopental	
	Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS).				
	The assay is intended as a test to screen for recent illicit drug abuse or intentional or inadvertent ingestion of prescription medication(s) as part of replacement therapy for opioid addiction, and/or as a confirmatory test to monitor patient's compliance with treatment replacement or abstention as part of a rehabilitation programme.				
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6				
GMDN Code	55458 "Multiple drugs of abuse IVD, kit, liquid chromatography"				
Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands		Identification No.	2797	
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX Chapters I and III				
Certificates issued	EU Quality management System Certificate (IVDR) IVDR 838647				

Declarations		
This EU declaration of conformity is issued under the sole responsibility of the manufacturer. The devices that are covered by the present declaration are in conformity with the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).		
Following Common Specifications were considered as part of determining device conformity with the IVDR:		
Not applicable as no Common Specifications exist for the concerned device.		
Additional information	n/a	
This EU declaration of conformity is issued by		
 Gräfelfing, September 15th, 2026 Michael Meier, Managing Director  Gräfelfing, September 15th, 2026 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	September 14 th , 2031	Version: 1.1