

EU DECLARATION OF CONFORMITY EUROPEAN UNION EC DIRECTIVES



Directive 2014/30/EU
Directive 2014/35/EU
Directive 2014/53/UE
Directive 2011/65/UE



Systems

Catalog numbers

TLC Explorer

1.52610.0001

The systems mentioned above are manufactured by Merck Life Science KGaA; Frankfurter Straße 250; 64293 Darmstadt

- ♦ facilities whose quality management system is approved by an accredited registering body to the ISO®9001 Quality System Standards.
- ♦ We certify that these Systems are designed and manufactured in application of the following European Council directives:

DIR2014/30/EU	Relating to Electromagnetic compatibility
DIR2014/35/EU	Relating to electrical equipment designed for use within certain voltage limits
DIR2014/53/EU	On radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity
DIR2011/65/UE	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), supplemented by the new Delegated Directive 2015/863/EU .

- ♦ We hereby declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following standards:
 - IEC61326-1 (oct. 2020) Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: general requirements.
 - IEC 61010-1 (Ed. 3) +AMD1 (2016-12) Safety requirements for electrical equipment for measurement, control, and laboratory use.
 - EN 301 489-17 v3.2.4 Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for Electro Magnetic Compatibility
 - EN 300 328, v2.2.2 (harmonized, accredited Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
 - EN 62311 (EMC), :2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)

SIGNATURE OF DECLARANT:

Christian GUILLERMOND

Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV. 2023**

DECLARATION OF CONFORMITY

In accordance with UK Government Guidance



Statutory Instrument 2016 No 1101
Statutory Instrument 2016 No 1091
Statutory Instrument 2016 No 3032
Statutory Instrument 2017 No 1206

**UK
CA**

Systems

Catalog numbers

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- ♦ The systems mentioned above are manufactured by Merck Life Science KGaA; Frankfurter Straße 250; 64293 Darmstadt
- ♦ We certify that these Systems are designed and manufactured in in conformity with the relevant UK Statutory Instruments and their amendments:

2016 No 1101	The Electrical Equipment Safety Regulations 2016
2016 No 1091	The Electromagnetic Compatibility Regulations 2016
2017 No.1206	The Radio Equipment Regulations 2017
2012 No 3032	The Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

- ♦ We hereby declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following standards:
 - IEC61326-1 (oct. 2020) Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: general requirements.
 - IEC 61010-1 (Ed. 3) +AMD1 (2016-12) Safety requirements for electrical equipment for measurement, control, and laboratory use.
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We certify that these Systems are designed and manufactured in application of the following standard:

UL 61010-1: Ed 3, 2012-05-11 Revised April 29, 2016: Safety requirements for electrical equipment for measurement, control and laboratory use.

CAN/CSA C22.2 No. 61010-1-12, 3rd Edition, Revision dated April 29, 2016, IEC 61010-1:2010 (Third Edition): Equipment for measurement, control and laboratory use; Part 1; General Requirement.

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- ♦ We certify that these Systems are designed and manufactured in application of the FCC standard and test method:
- ♦ Standards to which conformity is declared as applicable are the following:

STANDARDS (USA): FCC part 15: Code of federal regulations
Title 47 – Telecommunication chapter 1- Federal Communication Commission.
Part 15- Radio frequency devices Subpart B

TEST METHOD: Section 15 .107 for FCC Part 15
Section 15 .109 for FCC Part 15

REGISTRATION

FCC ID: **2ABCB-RPIRMO**



STANDARDS (Canada): ICES-003 Issue 6 January 2016 (Ref ANSI C63.4: 2014)
ICES -001 of 2020 ISSUE 5

REGISTRATION

ICES-001(B) / NMB-001(B)
IC: 20953:RPICM4

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**IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST
CERTIFICATES FOR ELECTRICAL EQUIPMENT
(IECEE) CB SCHEME**



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- ♦ We certify that these Systems are designed and manufactured in application of the International standard and test method:
- Standards to which conformity is declared as applicable are the following:



SAFETY:

STANDARD:

IEC 61010-1(ed.3.1)

CB TEST CERTIFICATE:

DK-146454-UL

File E216983 Vol. X2

EMC:

STANDARD:

IEC 61326-1(2020)

CB TEST CERTIFICATE:

DK-145619-UL

Access to CB certificate: <https://certificates.iecee.org/#/home>

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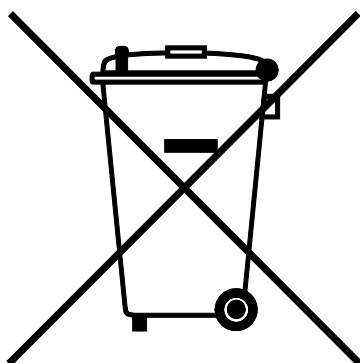
**Statement of Conformity to the European Union
Directive 2012/19/EU on Waste Electrical and Electronic
Equipment (WEEE)**



Systems

Catalog numbers

TLC Explorer	1.52610.0001
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EN – In the European Union, the crossed out wheeled bin symbol shown here signifies that this product must not be discarded with common solid waste at the end of its life. Instead, it should be collected as waste electrical and electronic equipment (WEEE) and sent to a facility where it may be recycled.

For information regarding how to recycle Merck Millipore electrical and electronic products, please visit our website:
<https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>



ES – En la Unión Europea, el símbolo de una papelera con una cruz que se muestra aquí significa que el producto no debe ser descartado con los residuos comunes al fin de su vida útil. En vez de eso, el producto debe ser recolectado como residuo de aparatos eléctricos y electrónicos (RAEE,

o WEEE) y enviado a una organización que lo pueda reciclar.

Para mayor información respecto de cómo reciclar aparatos eléctricos y electrónicos de Merck Millipore, por favor consulte nuestro sitio web: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

FR – Dans l'Union Européenne, le symbole d'une poubelle avec une croix (illustré ici) indique que ce produit ne peut pas être éliminé avec les déchets industriels banals. Il doit être collecté comme Déchet d'Équipement Électrique et Electronique (DEEE, ou WEEE) et être envoyé à un organisme spécialisé dans le recyclage d Déchet d'Équipement Électrique et Electronique

Pour de plus amples informations sur comment recycler les appareils électriques et électroniques de Merck Millipore, s.v.p. consultez notre site web <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

DE – In der Europäischen Union bedeutet das Symbol eines Behälters mit einem Kreuz, wie es hier dargestellt ist, dass das Produkt am Ende seiner Nutzungsdauer nicht mit dem Restmüll entsorgt werden darf. Stattdessen muss das Produkt wie Elektro- und Elektronik-Altgeräte (WEEE) gesammelt und über eine Organisation der Wiederverwertung zugeführt werden.

Weitere Informationen über das Recycling der Elektro- und Elektronikgeräte von Merck Millipore finden Sie auf unserer Website unter <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>



IT – Nell’Unione Europea, i cassoni contrassegnati con il simbolo raffigurato a fianco, stanno a significare che questi prodotti non dovrebbero essere eliminati con i comuni rifiuti solidi, alla fine della loro vita. Mentre essi dovrebbero essere raccolti come Rifiuti di Apparecchiature Elettriche ed Elettroniche (RAEE, o WEEE) ed inviati ai centri di raccolta che effettuano il loro riciclo.

Per informazioni che riguardano il come riciclare i prodotti elettrici ed elettronici di Merck Millipore, vi invitiamo a visitare il nostro sito web: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

PT – Na União Europeia, o símbolo de uma lata com um X que é mostrado acima, significa que o(s) produto(s) não deve(m) ser descartado(s) junto com o lixo comum, no final de sua vida útil. Em vez disso, o(s) produto(s) deve(m) ser recolhido(s), como resíduos de equipamentos elétricos e/ou eletrônicos (REEE, o WEEE) e enviado(s) para uma organização possa reciclar o(s) mesmo(s)

Para obter mais informações sobre como reciclar equipamentos elétricos e eletrônicos da Merck Millipore, consulte nosso site: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

NL – In de Europese Unie, het symbool van een bak met een kruis dat hier wordt getoond betekent dat het product niet moet worden weggegooid met het gemeenschappelijke afval na gebruik. In plaats daarvan moet het product worden verzameld als afgedankt(e) elektrisch(e) en elektronische apparatuur (AEEA of WEEE) en verzonden worden naar een organisatie die kan recyclen.

Voor meer informatie over hoe u elektrische en elektronische apparatuur te recyclen van Merck Millipore moet recyclen, zie onze website: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

SE – I Europeiska unionen innebär symbolen med en överkryssad soptunna som visas här, att produkten när den är utsliten inte får slängas tillsammans med vanligt brännbart avfall. Utan i stället bör den samlas in som elektriskt och elektroniskt avfall (WEEE) och skickas till en återvinningscentral.

För mer information om hur du återvinner elektriska och elektroniska produkter från Merck Millipore, se vår hemsida: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

PL – W Unii Europejskiej produktów oznakowanych symbolem przekreślonego kosza po zakończonym użytkowaniu nie należy wyrzucać razem z innymi odpadami do śmietnika. Tego typu produkty powinny być segregowane jako odpady zużytego sprzętu elektrycznego i elektronicznego (WEEE lub ZSEiE) i przekazywane organizacjom zajmującym się recyklingiem.

Więcej informacji na temat recyklingu sprzętu elektrycznego i elektronicznego Merck Millipore można uzyskać na naszej stronie internetowej: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

DK – I Den Europæiske Union betyder et kryds over en affaldscontainer, at produktet ikke må bortskaffes som almindeligt affald efter endt levetid. I stedet skal det indsamles som e-affald for elektronik og elektronsik udstyr (WEEE) og sendes til godkendte anlæg, hvor det vil blive genbrugt.

For mere information mht. bortskaffelse af Merck Millipore’s e-affald er du meget velkommen til at besøge vores hjemmeside: <https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling>

FI – Euroopan Unionin sisällä kuvassa oleva symboli (ristiinvedetyt viivat pyörillä varustetun roskasäiliön yli) merkitsee ettei tuotetta saa hävittää tavallisen jätteen tavoin. Sen sijaan se tulisi kerätä talteen elektronisena tai sähkölaitteena (WEEE), joka voidaan lähettää asianmukaiseen kierrätyskeskukseen.

Merck Milliporen sähköisten ja elektronisten laitteiden kierrätyksestä saa lisätietoa osoitteesta: [http://https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling](https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling)

Administrative Measure on the Control of Pollution Caused by Electronic Information Products



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产品中有毒有害物质或元素的名称及含量 - Table of Hazardous substances' name

Component name 部件名称		Toxic and hazardous substances and/or elements 有毒有害物质或元素					
		汞 (Hg)	镉 (Cd)	铅 (Pb)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
Mechanical Parts	Framework – Metal	O	O	O	O	O	O
	Housing – Plastic	O	O	O	O	O	O
Hydraulical Parts	Tubing and hydraulic connectors	O	O	O	O	O	O
	Pump head	O	O	O	O	O	O
	Manifold	O	O	O	O	O	O
Electrical Parts	Power supply / power cord / cable	O	O	X	O	O	O
	Actuator- Motor -Solenoid valves	O	O	O	O	O	O
	Sensors / Printed circuit board	O	O	O	O	O	O
	UV Lamp / Display	O	O	O	O	O	O
Printed Circuit Board (PWB)	PWB substrate/laminate	O	O	O	O	O	O
	Component and Connectors	O	O	O	O	O	O

O: 表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006 标准规定的限量要求以下

X: 表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006 标准规定的限量要求
(企业可在此处, 根据实际情况对上表中打“X”的技术原因进行进一步说明。)

O: Indicates that this toxic or Hazardous substances contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006

X: Indicates that this toxic or Hazardous substances contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006

SIGNATURE OF DECLARANT:

Cguillermond

Christian GUILLERMOND

Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV. 2023**

Declaration of Conformity for Wireless module embedded



Systems

Catalog numbers

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- ♦ facilities whose quality management system is approved by an accredited registering body to the ISO®9001 Quality System Standards.
- ♦ We certify that these Systems are designed and manufactured in application of the local standard and test method:
- Registration iD/ Numbers to which conformity are declared as applicable and valid are the following:

COUNTRY	ORGANISM	REGISTRATION NUMBER / ID
USA	FCC	2ABCB-RPIRMO
BRASIL	ANATEL	07601-21-10629
CANADA	ISED	20953:RPICM4
CHINA	SRRC /CMIIT	2023DJ15480
HONG-KONG	STC/ HKSTC LTD	CERTIFICATION No: HK0012303024
INDIA	Government of India Ministry of Communications Department of Telecommunications	REGISTRATION N°: ETA-SD-20230908578
JAPAN	MIC	D220018020 CERTIFIED NUMBER: 020-210202
SOUTH KOREA	NRRA	R-R-P2R-CM4
TAIWAN	NCC	内含發射器模組 CCAQ22Y10090T1

NOTE: Please note that certificate numbers are assigned to the RF module only.

SIGNATURE OF DECLARANT:

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