EU DECLARATION OF CONFORMITY EUROPEAN UNION EC DIRECTIVES

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

Systems	**Catalog numbers**
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- Millipore SAS - 67120 Molsheim (FRANCE) is the applicant of the equipment mentioned above.

- Millipore SAS Quality Management System is approved by an accredited registering body to the ISO® 9001 Quality System Standards.

- Millipore SAS certifies that the above referenced equipment is 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
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.**

Standards to which conformity is declared as applicable are the following:

- EN 62233: 2008: Measurement methods for electromagnetic fields with regard to human exposure.
- EN 61326-1 (Ed. 2) Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 61010-1 (Ed. 3.1) Safety requirements for electrical equipment for measurement, control and laboratory use.

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

Systems	**Catalog numbers**
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- Millipore SAS - 67120 Molsheim (FRANCE) is the applicant of the equipment mentioned above.
- Millipore SAS Quality Management System is approved by an accredited registering body to the ISO® 9001 Quality System Standards.
- Millipore SAS certifies that the above referenced systems are designed and manufactured 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
2012 No 3032	The Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment Regulations 2016

- 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:

- IEC 61326-1 (2012 Ed. 2) Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: general requirements.
- IEC 61010-1 (Ed. 3.1) Safety requirements for electrical equipment for measurement, control, and laboratory use.

SIGNATURE OF DECLARANT:

Christian GUILLERMOND
Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV 2023**

FCC DECLARATION OF CONFORMITY & ICES

Systems	Catalog numbers
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- Millipore SAS - 67120 Molsheim (FRANCE) is the applicant of the equipment mentioned above.
- Millipore SAS Quality Management System is approved by an accredited registering body to the ISO® 9001 Quality System Standards.
- Millipore SAS certifies that the above referenced systems are designed and manufactured in application of the FCC standard and test methods:
- Standards to which conformity is declared as applicable are the following:

STANDARDS (USA):

FCC part 15: 2014 Code of federal regulations
Title 47 – Telecommunication chapter 1- Federal Communication Commission.
Part 15- Radio frequency devices Subpart B- Unintentional Radiators Limits and Methods of measurement of radio disturbance.

STANDARDS (CANADA):

ICES-003 2017 and 2016

SIGNATURE OF DECLARANT:

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Medical Devices and Electrical Equipment Regulatory Management
DATE OF DECLARATION: **NOV 2023**

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

Systems	Catalog numbers
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- Millipore SAS - 67120 Molsheim (FRANCE) is the applicant of the equipment mentioned above.
- Millipore SAS Quality Management System is approved by an accredited registering body to the ISO® 9001 Quality System Standards.
- Standards to which conformity is declared as applicable are the following:

SAFETY:	STANDARD:	IEC 61010-1 (ed.3.1)
	CB TEST CERTIFICATE:	**IT-14854/M1**
EMC:	STANDARD:	IEC 61326-1 (ed.2)
	CB TEST CERTIFICATE:	**IT-14933, IT-14934, IT-14935**

Access to CB certificate: http://members.iecee.org/

SIGNATURE OF DECLARANT:

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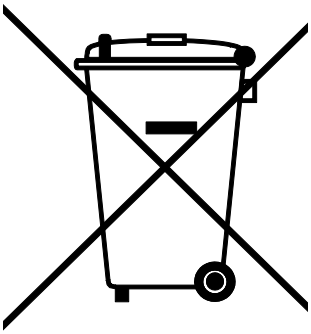
Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV 2023**

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

Systems	Catalog numbers
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01



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 KGaA, Darmstadt, Germany 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 KGaA, Darmstadt, Germany, 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'Equipement Electrique et Electronique (DEEE, ou WEEE) et être envoyé à un organisme spécialisé dans le recyclage d Déchet d'Equipement Electrique et Electronique

Pour de plus amples informations sur comment recycler les appareils électriques et électroniques de Merck KGaA, Darmstadt, Germany, 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 KGaA, Darmstadt, Germany 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.

er informazioni che riguardano il come riciclare i prodotti elettrici ed elettronici di Merck KGaA, Darmstadt, Germany, vi invitiamo a visitare il nosso 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 KGaA, Darmstadt, Germany, 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 worder naar een organisatie die kan recyclen.

Voor meer informatie over hoe u elektrische en elektronische apparatuur te recyclen van Merck KGaA, Darmstadt, Germany 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 KGaA, Darmstadt, Germany, 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 KGaA, Darmstadt, Germany 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. Istedet 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 KGaA, Darmstadt, Germany´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 KGaA, Darmstadt, Germanyn sähköisten ja elektronisten laitteiden kierrätyksestä saa lisätietoa osoitteesta: https://www.sigmaaldrich.com/FR/fr/life-science/quality-and-regulatory-management/recycling

Декларация о соотвествии Техническим Регламентам Евразийского Экономического Союза

Declaration of Conformity to the Technical Regulations of Customs Union (EEC)

Systems	Catalog numbers
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- **Упомянутые выше системы производятся на фабрике Миллипор САС, 67120 Мольсхайм, Франция (Millipore SAS - 67120 Molsheim - France). Система управления качеством данного производства соотвествует требованиям ИСО 9001, что подтверждено Аккредитованным регулирующим органом .**

The systems mentioned above are manufactured in Millipore SAS - 67120 Molsheim - FRANCE -facilities whose quality management system is approved by an accredited registering body to the ISO®9001 Quality System Standards.

- **Мы подтверждаем, что указанная выше продукция разработана и изготовлена в соотвествии с международными стандартами**

We certify that these systems are designed and manufactured in application of the International standard and test method:

- **На данную продукцию получены декларации о соотвествии Техническим Регламентам Таможенного Союза (Евразийского Экономического Союза):**
  - ✓ **"О безопасности низковольтного оборудования" ТР ТС 004/2011**
  - ✓ **" Электромагнитная совместимость технических средств" ТР ТС 020/2011**

Custom Union Technical Regulations to which conformity is declared as applicable are the following:

- ✓ *Safety of Low Voltage Equipment* *CU TR 004/2011*
- ✓ *Electro-magnetic Compatibility* *CU TR 020/2011*

Регистрационный номер декларации о соответствии: **ЕАЭС N RU Д-FR.Ая95.В.01232**

Дата регистрации декларации о соответствии: 15/01/2016

SIGNATURE OF DECLARANT:

Christian GUILLERMOND
Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV 2023**

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

Systems	Catalog numbers
STERITEST® SYMBIO PUMP	SYMBLFH01, SYMBISL01, SYMBFLE01, SYMBFBQ01

- The systems mentioned above are manufactured in Millipore SAS – 67120 Molsheim – FRANCE -facilities whose quality management system is approved by an accredited registering body to the ISO®9001 Quality System Standards.
- We certify that these BioMonitoring Instruments are designed and manufactured in application of the following standard: SJ/T 11364-2006 Marking for the Control of Pollution Caused by EIPs (EIP-A)

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□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 cord / cable	O	O	O	O	O	O
	Actuator- Motor -Solenoid valves	O	O	O	O	O	O
	Sensors	O	O	O	O	O	O
	UV Lamp	O	O	O	O	O	O
Printed Circuit Board (PWB)	PWB substrate/laminate	O	O	O	O	O	O
	Component and Connectors	O	O	X	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"×"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:

Christian GUILLERMOND
Medical Devices and Electrical Equipment Regulatory Management

DATE OF DECLARATION: **NOV 2023**