By Royal Charter

EC Certificate - Fu Qua ity Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01530**

[redacted]

5960 Heisley Road
Mentor
Ohio
44060
USA

In respect of:

The design and manufacture of sterile processing equipment, infection prevention systems
[redacted]

and for high level disinfection of medical devices

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[redacted]

By Royal Charter

EC Certificate Fu Qua ity Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No	**CE 01530**
Date:	**2019-01-04**
Issued to:	**STERIS Corporation**

[redacted]

5960 Heisley Road
Mentor
Ohio
44060
USA

Subcontractor:	**Service(s) supplied**
Corporation STERIS Canada (also operating as STERIS Canada ULC) [redacted] Québec G1C 8A3 Canada	**Manufacture**
STERIS Corporation 6100 Heisley Road Mentor Ohio	**Manufacture**

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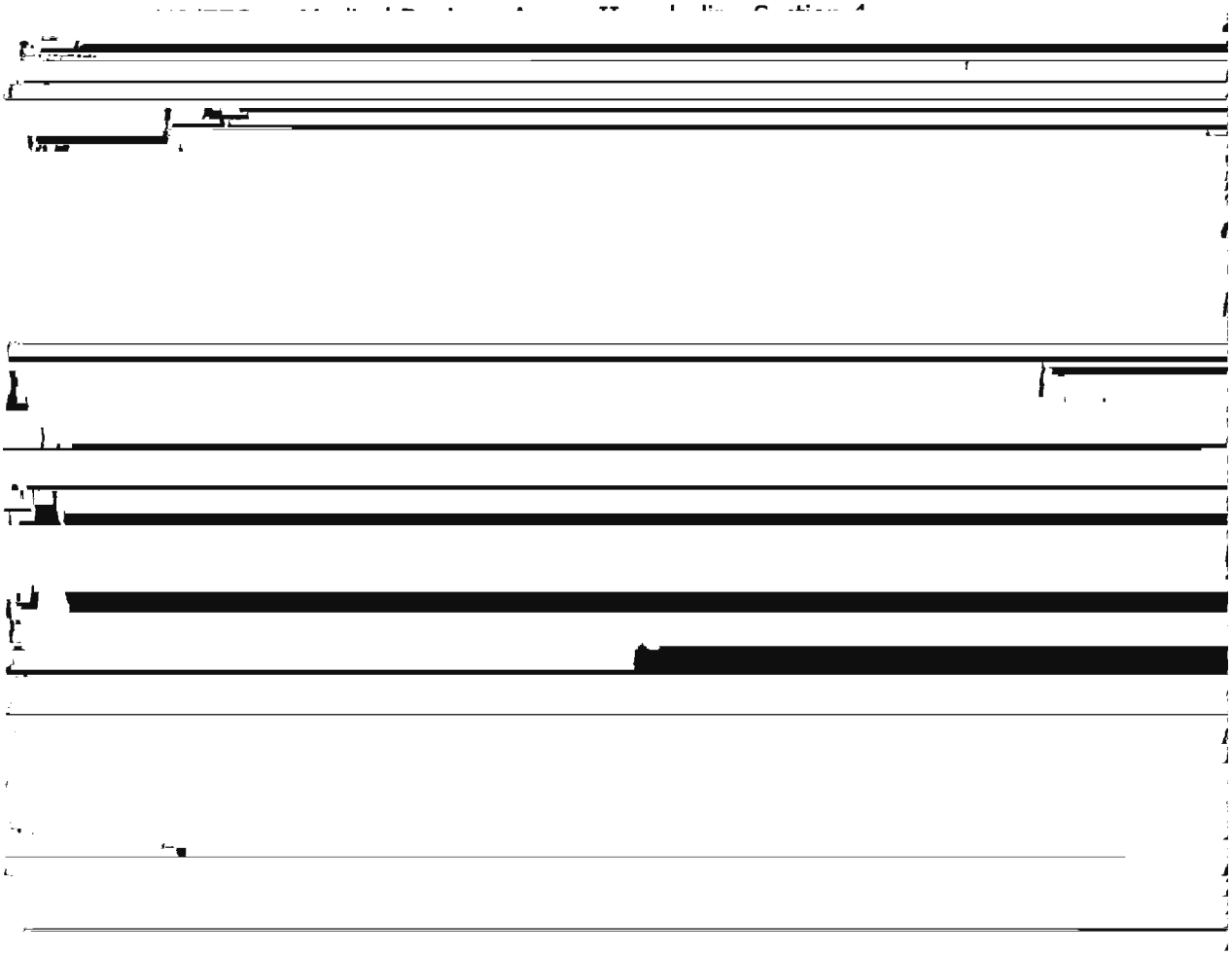
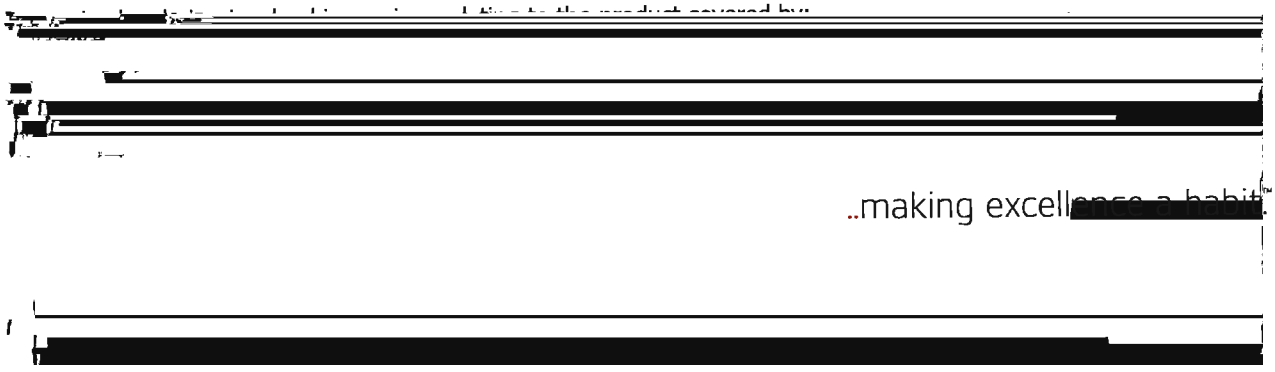
EC Certificate - Ful Qua ity Assurance System



List of Significant Subcontractors



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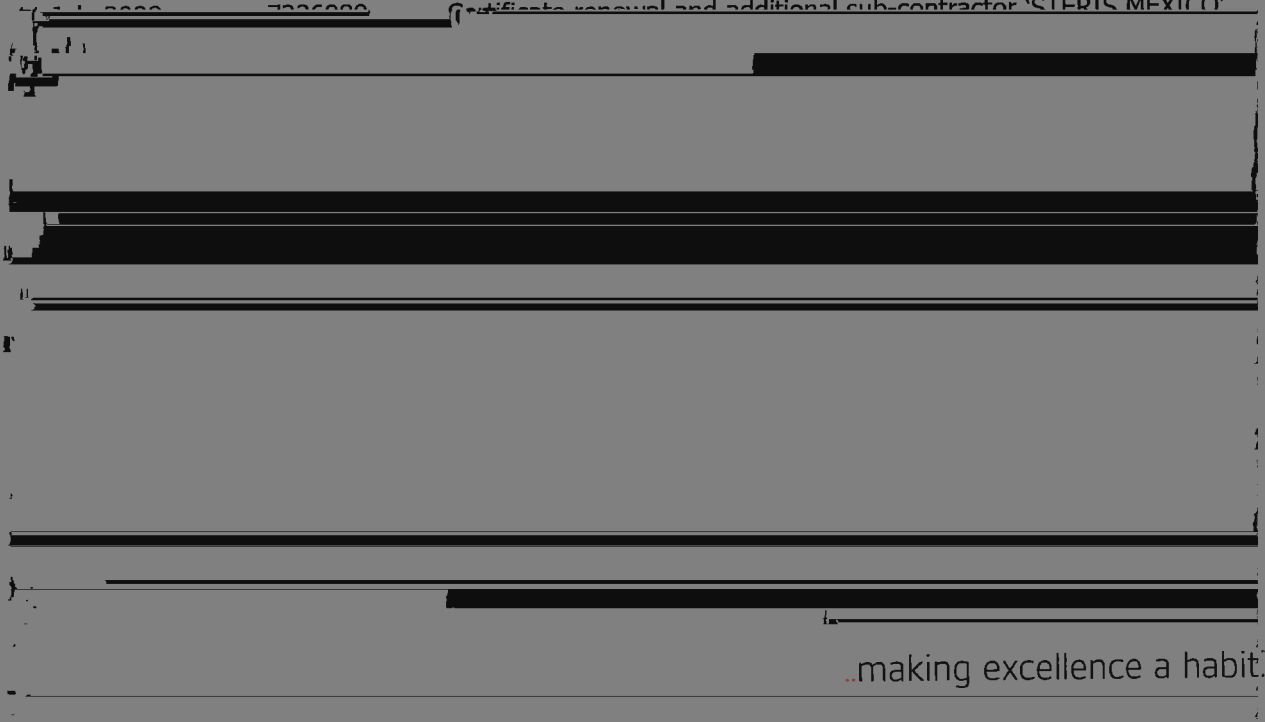
EC Certificate - Ful Qua ity Assurance System Certificate History

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**
5960 Heisley Road
Mentor
Ohio
44060
USA

Date	Reference Number	Action
20 January 1997		First Issue
09 July 2003		5 year renewal and addition of UK site for EU Regulatory activities (Vigilance).
16 March 2006		Scope clarification and the addition of disinfectants
[redacted]	[redacted]	[redacted]



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By Royal Charter

EC Certificate - Fu l Qua ity Assurance System

[redacted]

Certificate No: **CE 01530**

Date: **2019-01-04**

Issued To: **STERIS Corporation**

[redacted]

Mentor
Ohio
44060
USA

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless contractually arranged with BSI.

[redacted]

This certificate was issued electronically and is bound by the conditions of the contract.

[redacted]

USA

11 August 2023

Notified Body Confirmation Letter

Reference: EU2023-607/671105

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

[redacted]

SUSTAINABLE DEVELOPMENT GOALS

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Enspire 3000 Cleaning & Liquid Chemical Sterilant Processing System	Class IIa	SYSTEM 1 Express Sterile Processing System	EC certificate # 01530 Expiry date 2023-07-10 NB # 2797
V-PRO s2 & V-PRO max 2 Low Temperature Processing System	Class IIa	Not Applicable	# 01530 Expiry date 2023-07-10 NB # 2797

[redacted]

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

[redacted]

Date	Action
2023/08/11	Initial issue

SUSTAINABLE DEVELOPMENT GOALS

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

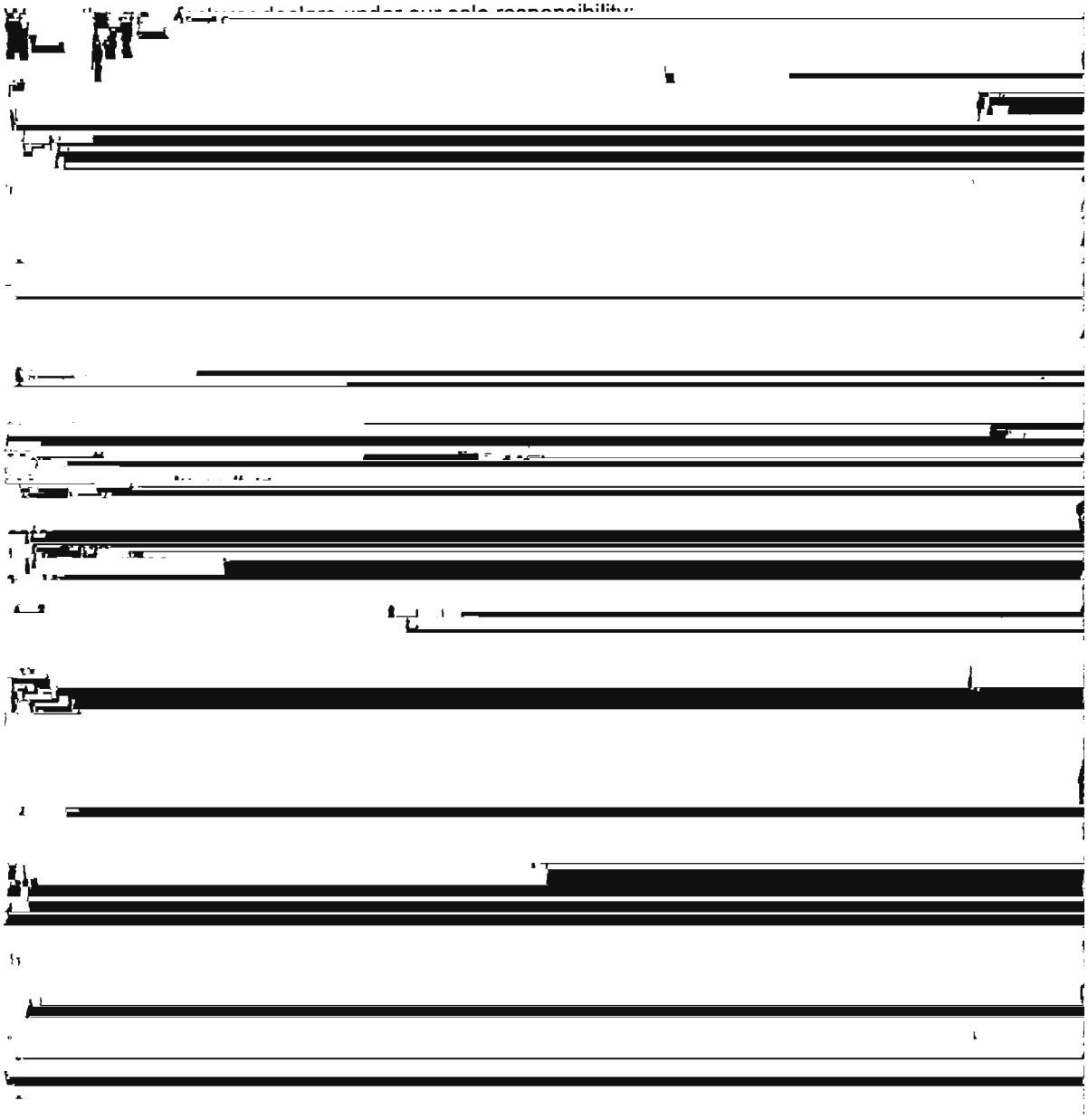
[redacted]

Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]

[redacted]

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which [redacted]

[redacted]



[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be

[redacted]

in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[redacted]

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the	Directive Certificate	Original expiry date as	Notified Body name and	End date of extended	Substitute Device(s)
[redacted]					

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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