



Studio 3
Channoeks Farm
Gilston
Harlow
Essex
CM20 2RL
United Kingdom

UKCA/CE Declaration of Conformity

To whom it may concern,

According to Article 120(3c) of the Medical Device Regulation (EU) 2017/745 (MDR), Shire Controls Ltd is allowed to market the following products under Class I CE marked medical devices:

- Area Alarms,
- Plant Alarms and
- Anaesthetic Gas Scavenging Systems

They have the NB extension that has been extended by Regulation (EU) 2023/607 and will end on either 31 December 2027 or 31 December 2028, depending on the device's risk class and subject to certain conditions.

The above-mentioned devices which previously fell under the Class I medical device category has now been up-classified to a Class IIb medical device as per the MDR (EU) 2017/745. Due to the recent submission of the new technical documentation required for this higher risk classification to the Notified Body for their review, we must await their formal approval before selling these devices as Class IIb products. This measure ensures compliance with the enhanced regulatory requirements and safeguards patient safety and product efficacy.

Issued on: 10-06-2024

Name: Clifford Caswell

Designation: Director

Signature:

A handwritten signature in black ink, appearing to read "Clifford Caswell", written in a cursive style.

Shire Controls Ltd.
Studio 3 Channoeks Farm, Gilston, Harlow
Essex CM20 2RL
United Kingdom

Our ref.: KOJ, Phone: 069 95427-542, Fax: -388
E-Mail: judith.koffler@dqs.de

Frankfurt a. M.,
28.05.2024

Ref. No. 31617724
Initial Assessment under VO (EU) Annex IX Chapter I and III

Dear Sir or Madam,

DQS Medizinprodukte GmbH, Notified Body according to Regulation (EU) 2017/745 concerning medical devices with Identification Number 0297 and located in August-Schanz-Straße 21, 60433 Frankfurt am Main, hereby confirms that:

Shire Controls Ltd.
Studio 3 Channoeks Farm, Gilston, Harlow
Essex CM20 2RL
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has submitted an application for a certification under Annex IX Chapter I and III and is currently in the planning phase for the initial assessment.

Yours Sincerely,

DQS Medizinprodukte GmbH



i. A. Andreas Dreimann
Senior Regulatory Affairs Manager



UK Declaration of Conformity

Shire Controls Ltd
Studio 3 Channoeks Farm
Gilston, Harlow, Essex
CM20 2RL United Kingdom

Product Trade Name SAXD Alarm

Product Description Area Alarms provide area alarm signals for piped medical gases. This type of alarm is typically installed near the point of use, such as in a patient room or operating theatre, and is designed to alert healthcare staff to any potential problems or issues within medical gas supply for the designated area. The device is designed to monitor high and low pipeline pressure for up to 6 gases.

GMDN code 44807

Risk Classification Class I

Model and Part Numbers:

SAXD 3Gas Display in 2 Gang Box – Flush	saxd3f
SAXD 3Gas Display in 2 Gang Box – Surface	saxd3s
SAXD 3Gas Display in SA6 Fascia Plate	saxd3sa6
SAXD 6Gas Display (2x3Gas) in SA6 Fascia Plate	saxd6sa6
SAXD 3Gas Display in SAX Flush Bezel	saxd3saxf
SAXD 3Gas Display in Surface Box	saxd3saxs
SAXD 6Gas Display (2x3Gas) in SAX Flush Bezel	saxd6saxf
SAXD 6Gas Display (2x3Gas) in Surface Box	saxd6saxs

Shire Controls Ltd, hereby declare, under our sole responsibility, that the above-mentioned products and models meet the relevant provisions of the UK Medical Device Regulations (MDR) 2002. The products meet the essential requirements of applicable directives / regulations and relevant standards.

Issued on: 16-03-2023

Name: Cliff Caswell

Designation: Director

Signature:

A handwritten signature in black ink, appearing to read 'Cliff Caswell', written in a cursive style.



UK Declaration of Conformity

Shire Controls Ltd
Studio 3 Channoeks Farm
Gilston, Harlow, Essex
CM20 2RL United Kingdom

Product Trade Name SAX6 Alarm

Product Description Area Alarms provide area alarm signals for piped medical gases. This type of alarm is typically installed near the point of use, such as in a patient room or operating theatre, and is designed to alert healthcare staff to any potential problems or issues within medical gas supply for the designated area. The device is designed to monitor high and low pipeline pressure for up to 6 gases.

GMDN code 44807

Risk Classification Class I

Model and Part Numbers:

SAX6 Alarm (Flush, Flush Deep or Surface) 1 Gas	sax1f	sax1s	sax1fd
SAX6 Alarm (Flush, Flush Deep or Surface) 2 Gas	sax2f	sax2s	sax1fd
SAX6 Alarm (Flush, Flush Deep or Surface) 3 Gas	sax3s	sax3f	sax1fd
SAX6 Alarm (Flush, Flush Deep or Surface) 4 Gas	sax4f	sax4s	sax1fd
SAX6 Alarm (Flush, Flush Deep or Surface) 5 Gas	sax5f	sax5s	sax1fd
SAX6 Alarm (Flush, Flush Deep or Surface) 6 Gas	sax6s	sax6f	sax1fd

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UK Declaration of Conformity

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CM20 2RL United Kingdom

Product Trade Name SA6 Alarm

Product Description Area Alarms provide area alarm signals for piped medical gases. This type of alarm is typically installed near the point of use, such as in a patient room or operating theatre, and is designed to alert healthcare staff to any potential problems or issues within medical gas supply for the designated area. The device is designed to monitor high and low pipeline pressure for up to 6 gases.

GMDN code 44807

Risk Classification Class I

Model and Part Numbers:

SA6 Alarm (Flush or Surface) 1 Gas	sa1f	sa1s
SA6 Alarm (Flush or Surface) 2 Gas	sa2f	sa2s
SA6 Alarm (Flush or Surface) 3 Gas	sa3s	sa3f
SA6 Alarm (Flush or Surface) 4 Gas	sa4f	sa4s
SA6 Alarm (Flush or Surface) 5 Gas	sa5f	sa5s
SA6 Alarm (Flush or Surface) 6 Gas	sa6s	sa6f

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Issued on : 16-03-2023

Name: Clifford Caswell

Designation: Director

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Doc Reference ID#SA6



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Product Trade Name SDX15 Alarm

Product Description SDX-15 Medical Gas Alarm system is a multiplexed system using the MEDCON data transmission. A pulse width modulated signal, capable of displaying up to 15 services, each consisting of up to 4 fault conditions (plus normal). Signals from Plant or other monitored equipment are fed into the system via transmitters located adjacent to the equipment.

A complete service can be transmitted from one transmitter or, if required, the service can be transmitted from several transmitters (i.e., Emergency Service Manifold for Plant located remotely to the Plant). In all cases, the transmitted channel(s) are selected by rotary switches.

The services are displayed at each panel as required; the service being selected by a rotary switch for each service within the panel (set to the corresponding transmitted channel for that gas/service).

GMDN code 44807

Risk Classification Class I

Model and Part Numbers:

SDX15 Alarms (Flush or Surface) 1 Gas	sdx1f	sdx1s
SDX15 Alarms (Flush or Surface) 2 Gas	sdx2f	sdx2s
SDX15 Alarms (Flush or Surface) 3 Gas	sdx3s	sdx3f
SDX15 Alarms (Flush or Surface) 4 Gas	sdx4f	sdx4s
SDX15 Alarms (Flush or Surface) 5 Gas	sdx5f	sdx5s
Plant To Alarm Interface	pa	

Shire Controls Ltd, hereby declare, under our sole responsibility, that the above-mentioned products and models meet the relevant provisions of the UK Medical Device Regulations (MDR) 2002. The products meet the essential requirements of applicable directives / regulations and relevant standards.

Issued on: 16-03-2023

Name: Clifford Caswell
Designation: Director

Signature:

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Doc Reference ID#SDX15



UK Declaration of

Conformity

Shire Controls Ltd
 Studio 3 Channoeks Farm
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 CM20 2RL United Kingdom

Product Trade Name: Anesthetic Gas Scavenging System

Product Description: The Shire Controls Ltd. Anaesthetic Gas Scavenging System is a system that actively removes anaesthetic gas mixtures from operating theatres and any other areas. It is an active system based on the suction of anaesthetic gas mixtures from operating rooms and others fitted with nitrous oxide terminal units. They are blower units, used to create a vacuum for the removal of waste anaesthetic gases in theatres. Waste anaesthetic gas, diluted by room air within the attached receiving system, is transmitted by vacuum generated by the exhauster unit of the scavenging system. Vacuum levels within the pipeline installation and flow rates at the terminal units are controlled by flow-regulating valves (also called pressure relief valves). Waste gas is safely discharged to the atmosphere via a fixed medical gas pipeline installation.

GMDN code: 36696

Risk Classification: Class I

Model and Part Numbers:

<u>Trade name: Duplex Anaesthetic Gas Scavenging System</u>	<u>Part Number</u>
Using 2no 230vac 50hz 0.4kw 3.1a Pumps	AGSS 1201d
Using 2no 415vac 50hz 0.4kw 1.4a Pumps	AGSS 1203d
Using 2no 230vac 50hz 0.85Kw 6a Pumps	AGSS 1301d
Using 2no 415vac 50hz 1.1kw 3a Pumps	AGSS 1303d
Using 2no 230vac 50hz 1.5kw 9a Pumps	AGSS 1411d
Using 2no 415vac 50hz 1.5kw 4a Pumps	AGSS 1423d
Using 2no 415vac 50hz 2.2kw 5.2a Pumps	AGSS 1523d
<u>Trade name: Simplex Anaesthetic Gas Scavenging System</u>	<u>Part Number</u>
Using 1no 230vac 50hz 0.4kw 3.1a Pumps	AGSS 1201s
Using 1no 415vac 50hz 0.4kw 1.4a Pumps	AGSS 1203s
Using 1no 230vac 50hz 0.85Kw 6a Pumps	AGSS 1301s
Using 1no 415vac 50hz 1.1kw 3a Pumps	AGSS 1303s
Using 1no 230vac 50hz 1.5kw 9a Pumps	AGSS 1411s
Using 1no 415vac 50hz 1.5kw 4a Pumps	AGSS 1423s

Shire Controls Ltd, hereby declare, under our sole responsibility, that the above-mentioned products and models meet the relevant provisions of the UK Medical Device Regulations (MDR) 2002. The products meet the essential requirements of applicable directives / regulations and relevant standards.

Issued on: 8th June 2023

Name: Clifford Caswell

Designation: Director

Signature:

A handwritten signature in black ink, appearing to read 'C Caswell', written in a cursive style.