Studio 3
Channocks 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: