



EC Declaration of Conformity to:

**Medical Devices Directive 93/42/EEC
RoHS 2 Directive 2011/65/EU
EMC Directive 2004/108/EC
Machinery Directive 2006/42/EC**

Legal Manufacturer:	CareFusion Switzerland 317 Sarl A-One Business Centre Zone d'activités Vers-la-Pièce N° 10 CH-1180 Rolle Switzerland
Manufacturer & Authorised European Representative:	CareFusion UK 305 Ltd The Crescent, Jays Close Basingstoke, Hampshire RG22 4BS United Kingdom
Device Type:	Alaris® Volumetric Infusion Pump
Device Description/Family:	Alaris® GW Volumetric Pump
EC Product Class:	II b
GMDN Number:	13215

Medical Devices Directive 93/42/EEC:

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993, are in accordance with Annex II Conformity Assessment Procedure, and have a registered Quality System as verified by BSI (British Standards Institution), Notified Body No. 0086 (EC Certificate No. 502238).

Where applicable, the following European Directives also apply:

RoHS2 Directive 2011/65/EU:

This Declaration of conformity is issued under the sole responsibility of Carefusion Switzerland 317 Sarl.

The object of this declaration is as listed in the product schedule below and is in conformity with Directive 2011/65/EU of the European Parliament and of Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is demonstrated in Carefusion document reference: 0300-005-000-SWI 'RoHS Directive Policy & Process'.



EMC Directive 2004-108-EC:

The object of this declaration is as listed in the product schedule below.

Conformity to this Directive to ensure the conformity of the apparatus with the provisions of this Directive is demonstrated by the EMC Directive checklist document ref: 0310-008-009-R-SD-INF and conformance to BS EN 60601-1-2: 2007.

Machinery Directive 2006/42/EC:

The Machinery identified herein fulfills all the relevant provisions of this Directive as verified by BSI (British Standards Institution), Notified Body No. 0086 (EC Certificate No. 502238).

Conformity to this Directive to ensure the conformity of the apparatus with the provisions of this Directive is demonstrated by the Machinery Directive checklist.

STED File: 002

Issue Level: 07

Signed:

A handwritten signature in blue ink, appearing to read "Robert Hofland", written over a large, faint circular stamp.

Robert Hofland

Date: **05 JUN 2015**

Director QRA, International



Product Schedule

Alaris® GW Large Volume Infusion Pump

GMDN Number: 13215

Part Number	Description	EC Product Class
25041ESD1	Alaris® GW, Spanish, Dedic, RS232	II b
25041GBD1	Alaris® GW, English, Dedic, RS232	II b
25041GBN1	Alaris® GW, English, Multidedic, RS232	II b
25041RWN1	Alaris® GW, Rest of World, Multidedic	II b
25042NLD1	Alaris® GW, Dutch, Dedic., RS232	II b
25042NLN1	Alaris® GW, Dutch, Multidedic., RS232	II b
25042GBD1	Alaris® GW, English, Dedic., RS232	II b
25042FRD1	Alaris® GW, French, Dedic., RS232	II b
25042FRN1	Alaris® GW, French, Multidedic., RS232	II b
25042DED1	Alaris® GW, German, Dedic., RS232	II b
25042DEN1	Alaris® GW, German, Multidedic., RS232	II b
25042ITD1	Alaris® GW, Italian, Dedic., RS232	II b
25042PTD1	Alaris® GW, Portuguese, Dedic., RS232	II b
25042ESD1	Alaris® GW, Spanish, Dedic., RS232	II b
25042RWN1	Alaris® GW, Rest of World, Multidedic.	II b
25042SED1	Alaris® GW, Swedish, Dedic., RS232	II b
25042CZN1	Alaris® GW, Czech, Multidedic., RS232	II b
25042POD1	Alaris® GW, Polish, Dedic., RS232	II b
25042HUD1	Alaris® GW, Hungarian, Dedic., RS232	II b
25042RUD1	Alaris® GW, Russian, Dedic., RS232	II b
25042DKD1	Alaris® GW, Danish, Dedic., RS232	II b
25042TRD1	Alaris® GW, Turkish, Dedic., RS232	II b
25042TRN1	Alaris® GW, Turkish, Multidedicated	II b
25042ESN1	Alaris® GW, Spanish, Multidedic, RS232	II b
25042FID1	Alaris® GW, Finnish, Dedic., RS232	II b
25042ELD1	Alaris® GW, Greek, Dedic., RS232	II b
25042SRD1	Alaris® GW, Serbian, Dedic., RS232	II b
25042ROD1	Alaris® GW, Romanian, Dedic, RS232	II b
25042SLD1	Alaris® GW, Slovenian, Dedic, RS232	II b
25042EED1	Alaris® GW, Estonian, Dedic, RS232	II b
25042LVD1	Alaris® GW, Latvian, Dedic, RS232	II b
25042HRD1	Alaris® GW, Croatian, Dedic, RS232	II b