EC Declaration of Conformity

EC Declaration of Conformity Annex II (excluding section 4) to Medical Devices Directive 93/42/EEC
Manufacturer: ALBYN MEDICAL S.L.
Manufacturer's Address: POLIGONO INDUSTRIAL CORDOVILLA calle D, nº 1, 31191 – CORDOVILLA – NAVARRA, SPAIN

Device/s: SMARTFLOW (Ref: 00004900EU)
Description: Urine Flowmeter
EC Product Class: IIa Rule 10 (Active Device for diagnosis)
CLASSIFICATION OF ME EQUIPMENT: CLASS II Medical equipment, externally powered, Flowscale (Internally powered ME Equipment), Type BF applied part.

Albyn Medical S.L. declares that device SMARTFLOW with reference 00004900EU conforms to the relevant provisions of the EC Council Directive 93/42/EEC and the amendment 2007/47/EC and is in accordance with Annex II (excluding section 4), as implemented by the European Union's Medical Devices Regulations, as verified by our Notified Body:

SGS United Kingdom Limited (Notified Body No. 0120)
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

Standards:

EN ISO 14971:2012
MEDDEV 2.12/2
MEDDEV 2.7/1 rev 4
MEDDEV 2.4/1 rev 9
EN 1041:2008
BS EN 62304:2006
EN 980:2008
EN ISO 14971:2012
EN 60601-1-6:2010
EN60601-1-1:2001

Safety:
UNE-EN 60601-1:2006/A1:2013
EMC:
UNE-EN 60601-1-2:2008 + Corr:2010 (Medical Electrical Equipment)
Emission:
UNE-EN 55011:2011+A1:11 (conducted and radiated emission)
UNE-EN 61000-3-2:2006 + A1:10 + A2:10 (Harmonics).
UNE-EN 61000-3-3:2009 (Voltage fluctuations).
Immunity:
UNE-EN 61000-4-2:10
UNE-EN 61000-4-3:07 + A1:08 + A2:11
UNE-EN 61000-4-4:05+A1:10
UNE-EN 61000-4-5:07
UNE-EN 61000-4-6:09

UNE-EN 61000-4-8:11
UNE-EN 61000-4-11:05

Albyn Medical S.L. confirms that no other application has been lodged with another Notified Body for the same device related Quality Management System.

Albyn Medical S.L. agrees to develop, implement and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Albyn Medical S.L. agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Albyn Medical S.L. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Albyn Medical S.L. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Albyn Medical S.L. agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, including significant design change to devices.

Signed by the Albyn Medical S.L. designated representative:

Gonzalo Buil
Quality Manager
24th of April of 2017