


Declaration of conformity				 ALBYN MEDICAL Smart Medical Group			
Description	EC Declaration of Conformity Smartscale			Document	SS14.1_3		
				Revision	3		
		Date	06/05/2015	Sheet	1	OF	1

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: SMARTSCALE

Description: Urine Flowmeter

EC Product Class: IIa

Declaration of Conformity

Albyn Medical S.L. declares that device SMARTSCALE 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)

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
6th of May 2015