Invotech Excel FZCO
Plot no. S21209
P.o. Box 262492
Jebel Ali Free Zone
Dubai - U.A.E

Declaration of Conformity

We
Invotech Excel FZCO

Ensures and Declares that,
the following medical devices of **class I** according to appendix IX are manufactured and finally inspected by us to meet the provisions of

Council Directive 93/42/EEC with amendment of 2007/47/EC Of 14 June 1993 Concerning Medical Devices

With regard to all type of products manufactured here by us under our sole supervision / responsibility in accordance with Annex V of above mentioned directive. We further declare that our following products will be supplied to our valued customer SPENGLER SAS against their purchase orders.

	Spengler		Invotech	
Product Type	Designation	Reference	Designation	Reference
Dermatoscope	JDERMA	JDERMA	SIGMA 1000	808-550-25
Mirror of Clar	MIROIR DE CLAR	570 150	MD 130	808-706-06
Mirror of Chardon	MIROIR DE CHARDON	570 260	MD 130	808-718-06
Otoscope	SMARTLED 5500	570 517	OMNI	808-482-02
Ophtalmoscope	VISIONLED 4000	570 007	OMNI	808-492-02

We hereby declares that the above mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health products (Medical Devices) Regulations.
We further declare that our all products are produced in conformity with EN ISO 13485:2016 and compliance with cGMP standard regulations.

Applied Standards
ISO 14971:2009, ISO 10942:2006 (Ophthalmic Instruments: Direct Ophthalmoscopes), ISO 15004-1, IEC 60601-1:2005

Quality Management System Certificate:
EN ISO 13485:2016 Certified by SGS UK Ltd.

EU Representative:

OBELIS s.a
Bd.Général Wahis 5310
30 Brussels, BELGIUM
Tel: +(32) 2.732.59.54
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E-Mail : mail@obelis.net

Notified Body:

SGS United Kingdom Limited:
202b, Worle Parkway, Weston-super-Mare
BS22 6WA, United Kingdom
Ph. # +44 (0) 151 350 6666

Authorized Signature

Quality Assurance Manager
24-01-2019

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