Manufacturer Infogene.lda, Instituto Pedro Nunes, Rua Pedro Nunes, 3030-199 Coimbra, Portugal,
Tel.: +351 239700327, Fax: +351 22700301 e-mail: geral@infogene.pt

EC DECLARATION OF CONFORMITY

Portuguese Law 189/2000, of 12 August;
Directive 98/79/EC of the European Parliament and the Council of 27th October 1998
on In Vitro Diagnostic Medical Devices (IVDD)

Manufacturer hereby under own responsibility declares that product covered by this declaration conform with Essential Requirements which apply to it amongst the listed in Annex I and further fulfill the obligations laid down in Annex III (2) to (5) and affix de "CE" marking in accordance with Article 7 of the Portuguese Law 189/2000, of 12th of August - a national transposition of the EC Directive 98/79/EC (IVD Directive) - and therefore does not endanger the health and safety of patients, users and third parties, provided that it is used in accordance with the purpose for which it was designed. Supporting documentation is retained under the premises of the manufacturer.

The aforementioned manufacturer has ISO9001:2015 quality certification and has implemented a quality management system for design, manufacture and final inspection of the devices in the framework of ISO13485:2016 covering: the organizational structure and responsibilities; manufacturing processes and systematic quality control of production; the means of monitoring the performance of the quality system. Quality management system further keeps up to date a process of systematic analysis of the experience with devices in the post-production phase and necessary corrective measures, taking into account the nature and risks related to the device.

Competent Authority will be notified of incidents relating to: any malfunction, damage or deterioration of the characteristics of the device, inadequate labeling or instructions that directly or indirectly are likely to cause or have caused health of patient users or third parties; any technical or medical reasons which, for the mentioned reasons, have led the manufacturer to systematic withdraw devices of the same genre from the market. This declaration, as well as the technical documentation, is made available to the Competent Authority for inspection purposes for five years from the last date of manufacture of the medical device.

Product Name/TradeMark Product Description Product References	UROMONITOR® Urine Test to Monitor Recurrence of Non-Muscle Invasive Bladder Cancer PFU01; PFU50; PADN50; RTPCR50
Authorized Representatives	U-MONITOR ; STELLA MARIS MEDICAL ALERTS
Manufacturer	Infogene.Lda IPN Incubadora, Edifício D, Rua Pedro Nunes, 3030-199 Coimbra, Portugal
Classification	Medical In-Vitro Diagnostic Devices not covered by Annex II and not intended for self-diagnosis
Conformity Assessment Route	Nrs. 2 – 5 of Annex III of Law 189/200; Annex III of IVDD

Signature:

Name: Hugo João Marques Prazeres
Title: Technical Director & Chief Executive Manager

Valid From: 08/02/2018

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