


EU Declaration of Conformity

(N° dc90154ben)

WE THE MANUFACTURER

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Single Registration Number	FR-MF-000000320

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	Hemostasis Analyzer
Product name	Yumizen G800h / Yumizen G850h
Basic UDI-DI	361023ymz_g800YQ
Country of origin	HUNGARY

Intended Use

The Yumizen G800h / Yumizen G850h is a fully automated blood coagulation analyzer. The instrument can analyze decalcified plasma samples using coagulation, chromogenic and immunoassay methods. The analyzed data can be stored, displayed and reported. The instrument has several built-in functions, including automatic reagent handling by barcode system, priority processing of STAT samples, quality control and preanalytical interference check for hemolysis, icterus and lipemia (HIL). A cap piercer unit is available on the Yumizen G850h (Yumizen G800h without cap piercer unit). For *in vitro* diagnostic use only.

MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS, STANDARDS AND COMMON SPECIFICATIONS

Regulations	Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices Risk Class: A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV (<i>Class A devices excluding sterile devices</i>)
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	EN 61010-1: 2010 + A1:2019 / EN 61010-2-101: 2017 / EN 61326-1: 2013
Common Specifications	Not applicable

Montpellier, France
2023/12/07

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