


EU Declaration of Conformity

(N° dc90182aen)

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	Clinical Chemistry Reagent
Product name	Yumizen C Ferritin / Yumizen C560 Ferritin
Models	1300148010 / 1300148011
Basic UDI-DI	361023ymz_cferritin2L / 361023ymz_c560ferritinME
Country of origin	JAPAN

Intended Use

Yumizen C Ferritin / Yumizen C560 Ferritin reagent is intended for the quantitative *in vitro* diagnostic determination of Ferritin in serum and plasma by latex-enhanced immunoturbidimetric assay. Clinical laboratories use.

Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia and is also biomarker of inflammation.

Assessing physiologic and pathologic variations of ferritin in human serum and plasma is useful for screening or follow-up of these diseases.

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 type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX IX (Chap I & III, chap II section 4 & 5.1) + ANNEX IV (<i>Class B & C self-testing and near patient testing devices</i>)	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V. Notified Body Identification: 2797
Common Specifications	Not applicable	

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