


EU Declaration of Conformity

(N° dc90181aen)

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 CRP / Yumizen C560 CRP
Models	1300147998 / 1300147999
Basic UDI-DI	361023ymz_ccrpEY / 361023ymz_c560crpMT
Country of origin	JAPAN

Intended Use

Yumizen C CRP / Yumizen C560 CRP reagent is intended for the quantitative *in vitro* diagnostic determination of the C-reactive protein in human serum and plasma based on an immunoturbidimetric assay.
Clinical laboratories use.

CRP is one of the strongest acute phase reactants and aids in non-specific host defence against infectious agents, rising after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation. This reagent is used to detect and measure C-reactive protein to assess the inflammatory status of the body.

Assessing physiologic and pathologic variations of C-reactive protein concentration in human serum and plasma is useful for screening or follow-up of inflammatory or infectious status.

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 type="checkbox"/> C <input checked="" type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV (<i>Class B & C devices excluding 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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