



EC DECLARATION OF CONFORMITY
According to Annex V and Annex VII of MDD 93/42/EEC

TF43 11 Aug. 2006
GMDN 16704

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the product :

GC Fuji TRIAGE®
GC Fuji TRIAGE® CAPSULE

to which this declaration relates, is in conformity with the following standards or other normative documents :

ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1:
Powder/liquid acid-base cements

ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1:
Evaluation and testing within a risk management process

ISO 7405: 2008 Dentistry - Evaluation of biocompatibility of medical
devices used in dentistry

EN ISO 13485:2016 Medical Devices -Quality Management Systems-
Requirements for Regulatory Purposes

and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).



Leuven,09/03/2021.....
Date

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Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.

LIST OF PRODUCTS

Article Code	New Article code	Description
013604	10006804	Fuji TRIAGE EP CAPSULE (50 pcs) PINK
013605	10006805	Fuji TRIAGE EP CAPSULE (50 pcs) WHITE
439990	10004442	FUJI TRIAGE PINK STARTER PKG
439991	10004443	FUJI TRIAGE WHITE STARTER PKG
439992	10004444	FUJI TRIAGE CAPSULE PINK (200) EXPORT BX
439993	10004445	FUJI TRIAGE CAPSULE WHITE (200) EXPORT
001946	10005104	Fuji TRIAGE CAPSULE (50 capsules) PINK
002269	10005136	Fuji Triage Capsules 50pcs. White
002490	10000387	Fuji Triage Pink 1-1 pack
002491	10000388	Fuji Triage White 1-1 pack
002495	10000389	Fuji Triage Pink box of 50 caps
002496	10000390	Fuji Triage White box of 50 caps
003295	10000585	Fuji Triage Pink 1-1 pack EEP
003296	10000586	Fuji Triage White 1-1 pack EEP
003297	10000587	Fuji Triage Pink box of 50 caps EEP
003298	10000588	Fuji Triage White box of 50 caps EEP
900490	10003284	Fuji Triage Pink 50+10 Caps Promo
900491	10003285	Fuji Triage White 50+10 Caps Promo
900519	10003299	Fuji Triage Pink 50 +10 Caps Promo EEP
900520	10003300	Fuji Triage White 50 +10 Caps Promo EEP
900689	10003348	GC Fuji Triage sample dentonauts
900690	10003349	GC Fuji Triage sample dentonauts EEP