EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#104 01 March 2013
GMDN 35876

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

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

everStick®COMBI

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick®COMBI is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#103 01 March 2013
GMDN 35876

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

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

everStick® INTRO

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® INTRO is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#102 01 March 2013
GMDN 35876

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

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

everStick®STARTER KIT

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick®STARTER KIT is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#95 01 March 2013
GMDN 35875

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

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

StickRESIN

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

StickRESIN is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, ...12/04/2013....
Date

.....
G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#94 01 March 2013
GMDN 44786

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

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

StickNET

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

APPLICABLE STANDARDS

EN ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

StickNET is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, ...12/04/2013....
Date

.....
G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#93 01 March 2013
GMDN 44786

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

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

Stick

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

APPLICABLE STANDARDS

EN ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

Stick is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#92 01 March 2013
GMDN 35868

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

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

everStick®POST INTRO

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick®POST INTRO is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/09/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#91 01 March 2013
GMDN 44786

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

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

everStick® NET

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® NET is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, ...12/04/2013...
Date

.....
G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#90 & 92 01 March 2013
GMDN 44786

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

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

everStick® POST

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® POST is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#89 01 March 2013
GMDN 44786

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

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

everStick® PERIO

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® PERIO is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#88 01 March 2013
GMDN 44786

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

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

everStick® ORTHO

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

APPLICABLE STANDARDS

EN ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® ORTHO is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven

EC DECLARATION OF CONFORMITY
According to Annex II.3 of MDD 93/42/EEC

TF#87 01 March 2013
GMDN 44786

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

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

everStick® C&B

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

APPLICABLE STANDARDS

ISO 9001:2008	Quality management systems. Requirements
ISO13485:2003	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.

everStick® C&B is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (NB 0086).

Leuven, 12/04/2013
Date

G. Blumental
Head Regulatory Department
On behalf of GC EUROPE N.V.