STENTYS DES(P) DECLARATION OF CONFORMITY

MANUFACTURER **STENTYS SA**
25 rue de Choiseul, 75002 PARIS, FRANCE

MEDICAL DEVICE **STENTYS DES(P)**
Type Model **STY01-3035-17, STY01-3035-22, STY01-3035-27**
STY01-3545-17, STY01-3545-22, STY01-3545-27
STY01-2530-17, STY01-2530-22, STY01-2530-27

Category	(07) Non Active Implantable Medical Device
Sub-Category	Coronary Stent System (Drug (Paclitaxel) Eluting Stent)
GMDN	Drug-eluting coronary artery stent, non-biodegradable-polymer-coated
MDD Classification	Class III – MDD – Annex IX – Rules 6,8 & 13

We herewith declare, as manufacturer and under our sole responsibility, that the above-mentioned medical device is in conformity with the
European Directive 93/42/EEC (The (MDD)
and fulfills the essential requirements of MDD -Annex I

This declaration is based on the following **CE Certificate(s)** issued by NSAI (0050)
According to **MDD - Annex II.3 & Annex II.4:**
No. 252.823 dated 2011-12-22.
& **Attachment** amended on 2012-08-16.

2013-02-08

PARIS

X

Luc MORISSET
STENTYS, QA & RA Director
Signé par : Luc MORISSET

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