Certificate Notification to the Commission and other Member States

IDENTIFICATION	
Notification from (CA Reference)[1]:	
Status Date (yyyy-mm-dd)[2]:	2017-06-09
MANUFACTURER	
Manufacturer Name: CL Medical Address: 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France E-mail:	Authorised Representative (mandatory for manufacturers outside EEA) Name: Address: E-mail:
NOTIFIED BODY	
Notified body number:	0086
Notified body name:	BSI
CERTIFICATE	
Certificate Number:	CE 648248
Directive & Annex:	Directive 93/42/EEC Annex II excluding section 4
Scope Description:	Design, manufacture and final inspection of meshes for treatment of male and female urinary incontinence, genito-urinary prolapse and cervical cerclage; polyester meshes for the treatment of genito-urinary prolapse by laparotomy and laparoscopy; and hernia surgical meshes.
Internationally recognised nomenclature term:	
Device names, if possible[3]:	I-STOP: Mesh for treatment of male and female urinary incontinence, genito-urinary prolapse and cervical cerclage Pelvi-STOP: Polyester mesh for the treatment of genito-urinary prolapse by laparotomy and laparoscopy Parié-STOP: Hernia surgical mesh
Date of issue (yyyy-mm-dd):	2016-04-21
Expiration date (yyyy-mm-dd):	2017-09-03
STATUS COMMENT	
Select 1) the Status Code that describes the change in the status of the certificate and 2) the corresponding reason code, denoted by the Status Comment.	
Status Code:	Withdrawn
Status Comment[4]:	03 compliance: Quality Management System failures
Reason for Decision/Comments:	Certificate cancelled due to lack of progress since suspension on 2016-11-23. Certificate was suspensded as: -Multiple major nonconformities were identified during the manufacturer's surveillance audit. -Manufacturer then aborted the audit before its

	completion. -Manufacturer failed to provide a satisfactory Corrective Action Plan for the nonconformities. -Manufacturer has unpaid invoices.
Effective date of change (yyyy-mm-dd):	2017-05-23

[1] Use the CA reference, if it is known. If it is not known, identify the Member State. The CA reference takes the form XX/CA/YY. XX is the EU abbreviation for the country and YY is the numerical identification of the CA, usually 01

[2] The Status Date is the date that the notification is communicated to Member States

[3] If there are a large number of devices covered by the certificate, the device names should be attached to this form

[4] A detailed explanation is to be given in the 'Reason for Decision/Comments' section, for Status Comments marked with a '++' symbols. On occasion, the NB may decide that a reduction certificate scope is necessary. In this case, the Status Code 'withdrawn' should be selected along with the Status Comment '16 NB reduces certificate scope++'

In accordance with the DA handbook, the DA may consider requiring certificate withdrawals and/or suspensions as a corrective action to notified body nonconformities where:

- there is a high potential danger of certificates of conformity being inappropriately issued and affected product being placed on the market.

The notified body should consider requiring certificate suspension, withdrawal or restriction in cases when, for example In accordance with EN ISO/IEC 17021,

- the legal manufacturer's quality management system has persistently or seriously failed to meet requirements
- the legal manufacturer does not allow surveillance or recertification audits or
- the certified client has voluntarily requested a suspension

or in accordance with EN 45011,

- in the event of changes significantly affecting the product's design or specification
- changes in the standards to which compliance of the product is certified
- changes in the ownership, structure or management of the supplier or
- in the case of information indicating that the product may no longer comply with the requirements of the certification system.