ANNEX XII

CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official languages of the Union.

2. Each certificate shall refer to only one conformity assessment procedure.

3. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 27.

4. The scope of the certificates shall unambiguously describe the device or devices covered:

   (a) EU technical documentation assessment certificates and EU type-examination certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose as indicated by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 24(6).

   (b) EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification and the intended purpose.

5. The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. EU quality management system certificates and EU production quality assurance certificates for class A sterile devices shall include a statement that the audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions.

8. Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

1. name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. if already issued, the SRN of the manufacturer referred to in Article 28(2);

5. date of issue;

6. date of expiry;

7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of this Annex;

8. if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;

9. reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;

10. examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);

11. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;

12. if applicable, information about the surveillance by the notified body;

13. conclusions of the notified body's conformity assessment with regard to the relevant Annex;

14. conditions for or limitations to the validity of the certificate;

15. legally binding signature of the notified body in accordance with the applicable national law.