KEMA Medical

DECLARATION OF CONFORMITY

Examples for the Manufacturers Declaration required by the MDD

As stated in the Medical Device Directive 93/42/EEC (MDD): The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written "Declaration of Conformity". This declaration must cover a given number of (identified specimens of) the products manufactured and (must) be kept by the manufacturer.

The manufacturer (or his authorized representative established in the Community) must, for a period ending at least five years after the last product has been manufactured, keep (make) "the Declaration of Conformity" at the disposal of (available to) the national authorities (for inspection purposes).

Relevant elements for the "Declaration of Conformity" can be found in Article 4 and 11 of the Medical Device Directive. The requirements are described in the Conformity Assessment Procedures. (MDD, Annex II through VII). The text of the declaration relates to the Conformity Assessment Procedure followed by the manufacturer and will be different for the different procedures. The form and lay-out of the declaration is not defined in the MDD, which means that the manufacturer can make his own choice for the presentation of the information. Examples for the Declaration of Conformity, with the intention to state the elements to be expected in the declaration, are given below for procedures in which the Notified Body is involved. Other configurations are possible, depending on the for the manufacturer present situation.

The Declaration of Conformity shall be sufficiently detailed to facilitate identification and traceability of the documents by which the conformity with the provisions of the EC-Directive can be shown and specifically concerning the products covered by the declaration. The declaration shall clearly state the products concerned, which may be one or more products or one or more product categories. It shall be possible at all times to correlate the Declaration of Conformity with the distributed CE marked products.

The CE-marking of the products distributed to the market is only allowed based on the availability of the Declaration of Conformity, which means in practice that the declaration has to be a controlled document. The declaration may be seen as the internal certification of the products concerned, made up by the manufacturer under his own responsibility. The declaration in this respect relates to the external (third party) certification made up by the Notified Body. Therefore, depending on the agreement made between the Notified Body and the manufacturer, the declaration can also be part of the certification documents serving the purpose of product registration under the certification issued and presented by the Notified Body.

The Declaration of Conformity (the manufacturers declaration) shall be presented to the Notified Body for review.

EXAMPLES DECLARATION OF CONFORMITY (Next pages)

Examples are given for the procedures Annex II, Class II products, Annex III and V, with and without product list, and Annex VII and V. The procedure Annex II for Class III products is comparable to Annex III and V, both elements product (design) certification and system certification are applicable, and the declaration can be combined from the presented examples. Annex IV and VI are not used very often and are not included in the examples.

LejaProducts *document identification*

DECLARATION OF CONFORMITY
medical devices for in vitro diagnostics

We hereby declare that the distributed CE marked products, specified in the annexed product list, in accordance with Annex III of the "EC-Directive", the Council Directive 98/79/EEC of 27 October 1998, concerning medical devices for in vitro diagnostics.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class *I*, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex III of the EC-Directive.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 9001:2000, Quality System Certificate with reference number 2060173, issued on *1 March 2004* and delivered by KEMA Quality BV.

This Declaration of Conformity covers microscopic slides as specified in the productlist belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

Leja Products BV
Luzernestraat 10
2153 GN Nieuw-Vennep
the Netherlands

Place and date of issue
Nieuw-Vennep,

J.P.W. Vermeiden, PhD., Director Research & Development

Annex: Product list

Annex to the Declaration of Conformity (Product list)

Leja Products *document identification*

PRODUCT LIST

(*Microscopic Slides*)

This productlist belongs to the Declaration of Conformity opgesteld by Leja Products BV and specifies the CE marked products concerned that Leja Products BV intends to distribute in conformity with the provisions of the Council Directive 98/79/EEC of 27 October 1998 concerning medical devices for in-vitro diagnostics. The following list identifies the products by *(name and type- /or/ model- /or/ article-number)* and by *(serial- /or/ lot- /or/ batch-number /or/ other time related information)*.

Product name	*Product code*
SCAC	SC 20-01-02 B
SCAC	SC 20-01-04 B

Nieuw-Vennep,

J.P.W. Vermeiden, PhD
Director Research & Development

Remarks:
The Product list has the advantage, among other things, that product modifications and additional (new) products only require an up-date of the product list. Depending on the systems used by the manufacturer other possibilities than presented above can be applied for identification of the products.