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*Leja Products BV*

**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, Quality System Certificate with reference number 2060173, first issued on *March 1<sup>st</sup> 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:

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

*Place and date of issue  
Nieuw-Vennep, March 1<sup>st</sup> 2010.*

J.B. van Dam, MSc.  
C.E.O. Leja Products BV



Annex: Product list

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Annex to the Declaration of Conformity (Product list)

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*Leja Products BV*

**PRODUCT LIST**

*(Microscopic Slides)*

This product list belongs to the Declaration of Conformity drafted 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

<u>Product name</u>	<u>Product code</u>
SCAC	SC 20-01-02 B
SCAC	SC 20-01-04 B
SCAC	SC 100-01-02-A



*J.B. van Dam, MSc.  
C.E.O. Leja Products BV*

*Nieuw-Vennep, March 1<sup>st</sup> 2010*

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