



Leja Products B.V.

Luzernestraat 10
2153 GN Nieuw-Vennep
The Netherlands

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E-mail info@leja.nl

Website www.leja.nl

EC DECLARATION OF CONFORMITY

According to Annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

We hereby declare that the following IVD products:

<i>Product name</i>	<i>Product code</i>
Counting Chamber	SC 10-01-04 B
	SC 12-01 C
	SC 20-01 C
	SC 20-01-02 B
	SC 20-01-04 B
	SC 20-01-08 B
	SC 100-01-02 A
	SC 100-01-02 B

Classified as: Class 1

Manufactured at the following site:

Leja Products B.V.
Luzernestraat 10
2153 GN Nieuw-Vennep
The Netherlands

Comply with all essential requirements of the Directive 98/79/EC.

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.

Date : 02 February 2016

Place: Nieuw-Vennep

A. L. Van Kappel
General Manager Leja Products BV



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EC DECLARATION OF CONFORMITY

According to Annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

We hereby declare that the following IVD products:

<i>Product name</i>	<i>Product code</i>
Counting Chamber	SC 10-01-04-B-CE
	SC 12-01-C-CE
	SC 20-01-C-CE
	SC 20-01-02-B-CE
	SC 20-01-04-B-CE
	SC 20-01-08-B-CE
	SC 100-01-02-A-CE
	SC 100-01-02-B-CE
	SC 10-01-04-B SCA

Classified as: Class 1

Manufactured at the following site:

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The Netherlands

Comply with all essential requirements of the Directive 98/79/EC.

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.

Date : 13 September 2016

Place: Nieuw-Vennep

A. L. Van Kappel
General Manager Leja Products BV