

# SUBMISSION OF A NEW OR MODIFIED QUALITY SYSTEM CERTIFICATE

## SOUSSION D'UN CERTIFICAT DE SYSTÈME QUALITÉ

Original Certificate/ certificat original: 745002450

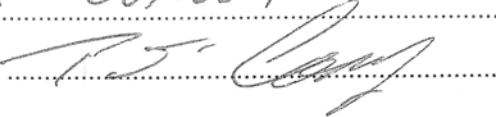
I, the manufacturer holding the original certificate above, hereby submit a new or modified version of my quality system certificate in accordance with section 43.1 of the Medical Device Regulations. The Licence numbers to which this certificate applies are listed below.

En tant que fabricant détenant le certificat original décrit ci-haut, je dépose chez Santé Canada une copie de la nouvelle version ou de la version modifiée de mon certificat de système qualité conformément à l'alinéa 43.1 du Règlement sur les instruments médicaux.

Name of Signing Official (print) / nom du signataire (lettres moulées SVP)

PETER COMLEY

Signed/signé:



Date:

24 August 2007

### Manufacturer Name and Address/ nom et adresse du fabricant

INSTITUT VIRION/SERION GMBH  
FRIEDRICH-BERGIUS-RING 19 WURZBURG, DE 97076

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Licence # No.d'homologation	Licence Name / nom de l'homologation	Class / Classe
69888	SERION ELISA CLASSIC HELICOBACTER PYLORI IGA	2
69890	SERION ELISA CLASSIC ADENOVIRUS IGG	2
69891	SERION ELISA CLASSIC FSME VIRUS/TBE VIRUS IGG (TICK BORNE ENCEPHALITIS)	2
69892	SERION ELISA CLASSIC INFLUENZA B VIRUS IGG	2
69893	SERION ELISA CLASSIC VARICELLA-ZOSTER VIRUS IGM	2
69894	SERION ELISA CLASSIC INFLUENZA B VIRUS IGA	2
69895	SERION ELISA CLASSIC FSME VIRUS/TBE VIRUS IGM (TICK BORNE ENCEPHALITIS)	2
69896	SERION ELISA CLASSIC VARICELLA-ZOSTER VIRUS IGG	2
69897	SERION ELISA CLASSIC VARICELLA-ZOSTER VIRUS IGA	2
69898	SERION ELISA CLASSIC RESP.SYNCYTIAL VIRUS IGA	2
69899	SERION ELISA CLASSIC RESP.SYNCYTIAL VIRUS IGG	2
69900	SERION ELISA CLASSIC PARAINFLUENZA VIRUS 1,2,3 IGA	2
69901	SERION ELISA CLASSIC PARAINFLUENZA VIRUS 2 IGG	2
69906	SERION ELISA CLASSIC PARAINFLUENZA VIRUS 1 IGG	2
69907	SERION ELISA CLASSIC PARAINFLUENZA VIRUS 3 IGG	2
69908	SERION ELISA CLASSIC MUMPS VIRUS/PAROTITIS/OREILLONS IGG	2
69909	SERION ELISA CLASSIC MUMPS VIRUS/PAROTITIS/OREILLONS IGM	2
69910	SERION ELISA CLASSIC MASERN VIRUS/MEASLES/ROUGEOLE IGG	2
69911	SERION ELISA CLASSIC MASERN VIRUS/MEASLES/ROUGEOLE IGM	2
69912	SERION ELISA CLASSIC INFLUENZA A VIRUS IGG	2
69913	SERION ELISA CLASSIC INFLUENZA A VIRUS IGA	2
69914	SERION ELISA CLASSIC BORDETELLA PERTUSSIS IGG (WHOOPING COUGH)	2
69915	SERION ELISA CLASSIC BORDETELLA PERTUSSIS IGM (WHOOPING COUGH)	2
69916	SERION ELISA CLASSIC BORDETELLA PERTUSSIS IGA (WHOOPING COUGH)	2
69917	SERION ELISA CLASSIC BORRELIA BURGDORFERI IGG (LYME DISEASE)	2
69931	SERION ELISA CLASSIC BORRELIA BURGDORFERI IGM (LYME DISEASE)	2
69932	SERION ELISA CLASSIC ADENOVIRUS IGA	2
69933	SERION ELISA CLASSIC HELICOBACTER PYLORI IGM	2
69934	SERION ELISA CLASSIC HELICOBACTER PYLORI IGG	2
73149	SERION ELISA CLASSIC ROETELN VIRUS/RUBELLA VIRUS IGG	3
73165	SERION ELISA CLASSIC HERPES SIMPLEX VIRUS 1/2 IGG	3
73166	SERION ELISA CLASSIC ROETELN VIRUS/RUBELLA VIRUS IGM	3