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Date: 14/11/2005

Ref: 209/MKT/E/68

SUBJECT **bioelisa Syphilis 3.0:
Product registration**



**This is to announce that the biokit
product:**

bioelisa Syphilis 3.0

3000-1148 96T / 3000-1149 480T

**has recently been approved and registered
by the Canada Ministry of Health.**

**In addition to this, bioelisa Syphilis 3.0 has
been reassessed by the Scottish National
Blood Transfusion Service. bioelisa
Syphilis 3.0 remains on the list of
approved tests suitable to be used by
Scottish blood banks.**

**Please find attached a copy of these two
awards.**



Medical Device Licence

Homologation d'un instrument médical

Licence Number: 69623

No d'homologation:

First Issue Date: 2005/10/28

Première date de délivrance:

Device Class/Classe de l'instrument: 3

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

BIOELISA SYPHILIS 3.0

Manufacturer Name & Address/Nom du fabricant & adresse

BIOKIT S.A.

CAN MALE
LLISSA D'AMUNT, BARCELONA
SPAIN
08186

Omer Boudreau, Director General, Therapeutic Products Directorate/Directeur général, Direction des produits thérapeutiques

Application Number: 90468
Numéro de la demande:

Manufacturer ID: 111693
Identificateur du fabricant:



Scottish National
Blood Transfusion Service
Ellen's Glen Road
Edinburgh EH17 7QT
Telephone 0131 536 5700
www.snbtn.org.uk



Mr M Hutchison
Biokit Limited
Ash House
Ash Road
New Ash Green
Longfield
KENT DA3 8JD

Date: 12 July 2005
Your Ref:
Our Ref: imf/cjl/2004/MTEG028a

Enquiries to: Susan Ryan
Extension: 65725
Direct Line: 0131 536 5725
Email: susan.ryan@snbtn.csa.scot.nhs.uk

Dear Mr Hutchison

BIOKIT BIOELISA SYPHILIS 3.0 (3000-1148/3000-1149)

I am writing to inform you that the above assay has been reassessed by the SNBTS Microbiology Test Evaluation Group (MTEG).

I confirm that this is acceptable for use within SNBTS/NIBTS and should remain on the SNBTS/NIBTS list of approved tests.

Yours sincerely

Professor Ian M Franklin
National Medical & Scientific Director

cc. Dr B C Dow