SCIENTIFIC INSTITUTE OF
PUBLIC HEALTH
Louis Pasteur

Section of Biosafety and Biotechnology
Dr.W. Moens

BIOSAFETY COUNCIL

SECRETARIAT

Reference: WIV/1520/DB/98-758
Your reference:
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To whom it may concern

CERTIFICATE

Subject: Assessment (dossier-based) of the effectiveness, in terms of inactivating biologically contaminated waste, of the combined microwave-steam sterilisation process in the waste disinfection device "SINTION 1.1" (MIDES, Graz, Austria).

Ordered by: FABETEC Europe S.P.R.L.
Boulevard Louis Schmidt 46 Bte 11
1040 Brussels - Belgium

It is hereby certified that the Service of Biosafety and Biotechnology (SBB) has assessed the effectiveness, in terms of inactivating biologically contaminated waste, of the combined microwave-steam sterilisation process in the waste disinfection device "SINTION 1.1". This assessment was performed especially on the basis of a dossier supplied by FABETEC. A detailed report of this assessment is available (reference IPH/1520/DB/98-366).

The SBB concludes that, from the theoretical point of view, the waste disinfection device "SINTION 1.1" is effective for the pre-treatment (inactivation) of biologically contaminated waste resulting from healthcare activities, provided that the operating instructions and safety regulations described by the manufacturer in its operating manual are strictly observed.

In optimal conditions, inactivation is effective against bacteria, fungi, parasites, viruses as well as bacterial and fungal spores. Inactivation of non-conventional agents (like prions) and sterilisation of clinical material were not considered. Moreover, the sterilisation process is not guaranteed on waste containing or consisting of hermetically closed containers (vapour- and air-tight).

The SBB nevertheless considers that the theoretical effectiveness of the device does not give an absolute guarantee that biologically contaminated waste gets finally inactivated. In this respect,

appropriate operational parameters (in accordance with the volume and composition of waste) should be determined for the specific conditions encountered in the laboratory.

The SBB strongly recommends that the effectiveness of the inactivation of biologically contaminated waste is **validated on a case by case basis** and is linked together with the **implementation in the laboratory of a coherent and appropriate waste management plan**.

Brussels, September 10, 1998.

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