

Translation from German into English language

To whom it may concern

Your reference:

Your message of:

Our reference:

Date:

0771LUS

15/10/2008

Ref: Opinion concerning the waste treatment plant SINTION of the manufacturer Christof Systems GmbH (formerly: CMB Maschinenbau & Handels GmbH)



Dear Sir/Madam,

TÜV Austria as the notified body for medical devices hereby delivers the following opinion upon request of the company Christof Systems GmbH (formerly: CMB Maschinenbau & Handels GmbH):

Specific question to be addressed:

Is the waste treatment plant SINTION manufactured by the company CMB Maschinenbau & Handels GmbH a medical device within the meaning of EU Directive 93/42/EEC?

Opinion and statement of grounds:

According to the manufacturer's specifications, the intended purpose of the waste treatment plant SINTION is described as the disinfection and sterilization of infectious medical waste from hospitals, clinics, and laboratories. This is achieved through a combination of microwaves and saturated vapour without chemical additives.

The objective is to transform infectious medical waste into residual waste.

Pursuant to EU Directive 93/42/EEC of 14 June 1993, Article 1, a device shall be treated as a medical device, if the same is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease ;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,;
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

In the opinion of TÜV Austria, the waste treatment plant SINTION is not characterized by the specific purpose mentioned above, and shall, therefore, not be classified as a medical device.

Due to a lack of direct connection with a medical device, the term "accessories" is also not applicable in this regard.

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Accredited as:
Inspection body,
Monitoring body,
Certification body,
Calibration
laboratory, office of
weights and
measures, first-time
inspection body and
boiler inspection
body

Notified Body 0408

Chairman of the
Supervisory Board:
KR Dipl.-Ing. Johann
MARIHART

Managing Directors:
Dipl.-Ing. Dr. Hugo
EBERHARDT
Mag. Christoph
WENNINGER

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branch offices : Dornbirn,
Graz, Innsbruck,
Klagenfurt, Linz,
Salzburg, St. Pölten
Wels, Vienna 1, Vienna
20,
Vienna 23, Brixen (1) and
Filderstadt (D)

Competent companies'
register court/
.number:
Vienna/ FN 288476 f

Bank account details:
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IBAN
AT! 53100000-04093282
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VAT No.
ATU63240488
DVR 3002476

Documents provided by the manufacturer::

- 1) Operating instructions applicable for SINTION 1.1, ID-No.: 1-01-90-002, as of 12/2005, submitted via email on 9th October 2008
- 2) Information leaflet waste treatment plant SINTION submitted via email on 9th October 2008
- 3) EC declaration of conformity No. 011/01 of 2nd June 2003, Mr. Gerhard Reiterer



Yours sincerely,
TÜV AUSTRIA SERVICES GMBH
Medizintechnik/ Nachrichtentechnik/ EMV

Dipl.-Ing. Emilia Lusnik