

OFFICE OF HEALTH  
AUTHORISATION AND ADMINISTRATIVE PROCEDURES  
DEPARTMENT OF MEDICAL DEVICES



Address: H-1051 Budapest, Zrínyi utca 3.  
Hungary  
Telefon: (+36-1) 302-5060, 235-7914  
Facsimile: (+36-1) 269-1255  
PO Box: H-1380 Budapest, Pf.: 1188.  
Internet: <http://www.eekh.hu>  
E-mail: [amd@eekh.hu](mailto:amd@eekh.hu)

Subject: Allpresan Diabetic Foam Cream  
Reference: 3707-002/2012/OTIG  
Admin.ref.: Eszter Ádám  
Date: 19 January 2012

**nsc Pharma GmbH & Co. KG**  
Dörte Schwarting Referentin Qualitätsmanagement

Mergenthaler Straße 40  
D-48268 Greven - Germany

Dear Sir,

Referring to your e-mail message received in relation with your product type Allpresan Diabetic Foam Cream on 10 May 2011 I shall provide the following information.

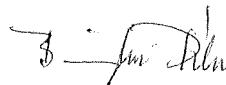
In Hungary we have the decree no. 4/2009. (III. 17.) EüM for medical devices. This is a harmonized decree containing regulation compatible with the Council Directive 93/42/ECC concerning medical devices (hereinafter referred as to MDD) as well as the Council Directive 90/385/ECC on active implantable medical devices.

Hungary is one of the EU Member States. If the procedures have been conducted according to the provisions of the MDD e.g. in Germany or in another Member State of the EU then marketing of the medical devices shall be possible. It is not necessary any further registration or conformity assessment in Hungary. Of course the essential requirements (e.g. language requirements, etc.) should be fulfilled according to the above-mentioned Hungarian decree.

In our previous letter (Ref.: 23315-005/2011/OTIG) we informed you that in order to clear the status of the Allpresan Diabetic Foam Cream our Office contacted the National Institute of Pharmacy of the National Institute for Quality- and Organizational Development in Healthcare and Medicines (hereinafter referred to as National Institute of Pharmacy). According to the information received from the National Institute of Pharmacy the Allpresan Diabetic Foam Cream can be classified as medical device.

On the basis of the presented documents (Declaration of Conformity, Certificate No. 7033GB410101126 issued by the Notified Body MEDCERT (Identification No.: 0482), labeling and Instructions for Use in four languages including Hungarian language) for the Allpresan Diabetic Foam Cream procedures has been conducted according to the MDD. It is not necessary any further registration or conformity assessment in Hungary.

Looking forward to hearing from you

  
Péter Bunyitai  
/Head of Department

