

# OTOSAN®

**DECLARATION OF CONFORMITY OF A  
MEDICAL DEVICE OF CLASS 1  
IN ACCORDANCE WITH THE EUROPEAN DIRECTIVE  
93/42/CEE OF 14 JUNE 1993**

I, the undersigned Massimiliano Gianardi, in my capacity as legal representative of the company Otosan, having its seat in Forlì (Italy), at via degli Scavi 32, registered with the n.233418 of the General Register of Italian Companies of the Chamber of Commerce of Forlì-Cesena,

**declare**

that our product named “OTOSAN-CONE FOR THE EAR CARE” is recognized as Medical Device of class 1 (non-sterile), in accordance with the applicable provisions defined by the Directive of the European Council 93/42/CEE of 14 June 1993 and subsequent modifications and integrations.

Additionally we declare to have prepared and keep constantly updated the technical files according to the provisions of Annex VII, section 3 of the same Directive.

The aforesaid literature is available for consultation purposes by the competent national bodies at the seat of the firm Otosan.

OTOSAN  
Massimiliano Gianardi  
(Legal Representative)

Forlì, January 10<sup>th</sup>, 2006