CLASSIFICATION

The medical devices *"*ANTIFUNGAL PLASTERS*"*, being the subject of this Technical Dossier, were classified as medical devices belonging to **class I** ("*Non-invasive devices*....") in accordance with Rule 1 of paragraph 1.1 "Non-invasive devices" of Annex IX of the Italian Legislative Decree 46/97, transposing the European Directive 93/42/EEC, as subsequently amended, i.e. as amended for example by the Italian Legislative Decree No. 37 of 25 January 2010, transposing the European Directive 2007/47/EC.

We consider the medical device covered by this technical dossier as belonging to: "medical devices ..... for the purpose of..... monitoring, treatment or alleviation of disease" in accordance with article 1, paragraph 2, letter a), of the Medical Device Directive 93/42/EEC (MDD).

Rule application

The following family of medical devices *"*ANTIFUNGAL PLASTERS*"*, belonging to class I, must meet the essential requirements set forth under Annex I and be produced in compliance with the provisions of Annex VII of the MDD.

The aforesaid devices consist of urea plasters and discs (capable of modifying the pH of the environment in which they are applied) used for the topical treatment of toenails and fingernails mycoses. This classification results from the fact that the plaster is applied exclusively on the nail affected by onychomycosis and featuring intact skin.

USEFUL LIFE OR EXPIRY

The expected life of the product in question is equal to five years, in its unopened and sealed packaging, provided it is kept far from direct heat sources.

As suggested also on the instructions for use (IFU), the time of use of the plaster corresponds to a daily use, after which it is replaced with a new one for a treatment from 1 to 3 weeks and in any case until the mycosis is completely removed.

Note: *within this technical dossier, when the abbreviation "MDD" is used, the following sentence is meant in its entirety: "Italian Legislative Decree 46/97 transposing the European Directive 93/42/EEC, and its subsequent amendments, such as those provided for by the Italian Legislative Decree No. 37 of 25 January 2010, which transposes the European Directive 2007/47/EC"*

NOTIFIED BODY

Not applicable because medical devices belong to class I (non-sterile and without measuring function).

DECLARATION OF CONFORMITY

Do. Tobell S.r.l., as manufacturer and solely responsible entity for the medical devices placed on the market in its own name, hereby declares that the devices covered by this Technical Dossier comply with the essential requirements provided for by Annex I of the Directive 93/42/EEC as subsequently amended (European Directive 2007/47/EEC).

The Declaration of Conformity of the "ANTIFUNGAL PLASTERS" family of medical devices is enclosed to this Technical Dossier.

MANUFACTURER

The following document outlines the set of technical, procedural and organizational solutions put in place by Do. Tobell S.r.l. to attain the compliance of its products to the European directive on medical devices, thus justifying the use of the CE mark.

This dossier illustrates the obligations fulfilled by Do. Tobell S.r.l. for the purpose of marketing its medical devices according to the provisions of the Italian Legislative Decree No. 46 of 24 February 1997 (and subsequent amendments and additions, including Italian Legislative Decree 37/2010).
Do. Tobell S.r.l. is therefore identified as manufacturer pursuant to the aforementioned law.

The trade name and complete address of the manufacturer is:

Do. Tobell S.r.l.
Via dell'Artigianato 32
I-36030 SARCEDO (VI)

The procedures implemented by the Company within its Quality Management System and required in order to meet the mandatory requirements set forth by the European Directive 93/42/EEC and subsequent supplementary amendments (e.g.: European Directive 2007/47/EC) are provided for in the document "EM 001" being an integral part of this technical dossier.