

Messrs  
Industrie Plastiche Lombarde SpA  
Via L. da Vinci 13C  
21023 Besozzo VA

Zola Predosa, 25/06/2010

Ref. Your Order of the 19/05/10

**REPORT N.1136-4/10**

**CONFORMITY TO USP XXXII Ed.2009 CLASS VI AND OTHER NORMATIVE REFERENCES**

Test Substance

Description: Pharmasteel  
Code: J4 01 015.1000.4  
Lot: CO 3561 del 29/04/2010  
Sterilization: n.r.  
Receipt number: 1136  
Receipt date: 21/05/2010  
Sampling carried out by: Industrie Plastiche Lombarde SpA

**Scope**

The samples above described were submitted to the tests listed in Table in order to demonstrate their biocompatibility according to USP XXXII Ed. 2009 Class VI and other normative references.

**Table**

Test	Test Report	Normative references
Intracutaneous reactivity test in the rabbit	1136-1/10	USP XXXII Ed.2009 ISO 10993-10: 2002/Amd 1: 2006
Acute systemic toxicity test in the mouse	1136-2/10	ASTM F 750-82 USP XXXII Ed. 2009 ISO 10993-11 : 2006
Implantation test in the rabbit	1136-3/10	USP XXXII Ed. 2009

**CONCLUSIONS**

Referring to the above listed Test Reports the Test Substances meet the requirements of USP Class VI and considered normative references.

Study Director: Giovanni Bassini, Ch. Eng.

