

DECLARATION
UNITED STATES PHARMACOPEIA – USP CLASS VI

Date : July 2015

Rev.1

We hereby confirm that representative samples of

PTFE G400

have been tested in accordance with USP protocol and meet the requirements of
USP Class VI plastic.

Results of tests are stated in the following Test Reports :

- Report No. S-2013-01361SAMi released 26th July 2013 for
 - Biological reactivity test, in vivo - Systemic injection test (USP 36<88>)
 - Biological reactivity test, in vivo - Implantation test (USP 36<88>)
 - Biological reactivity test, in vivo - Intracutaneous test (USP 36<88>)

and

- Report No. S-2013-01373SAMi released 27th June 2013 for
 - Cytotoxicity for elution test – (USP 35<87>)

Notes

It remains the responsibility of the customer use the plastic article manufactured from the product into the intended use, to assess the final suitability of the plastic material for the intended application . i.e. checking if the physical properties of plastic material make it suitable for the intended application, checking compliance of the finished plastic article with the relevant limits, checking for possible influence of the plastic material on the composition etc.

- The articles shall be thoroughly cleaned prior their first use.
- It is the responsibility of the buyer to assure traceability of the material during any further downstream use up to and including the finished machined part as well as the equipment in which it is assembled.

These tests on representative samples may not reflect results on articles made from these materials, especially if other substances are added during fabrication.

Testing of the finished article is the responsibility of the manufacturer or seller of the finished product if certification that meets USP standards is required.

Note No. 2 : The customer must always specify in the Orders when an approval / certification stated in this document is necessary. This because the approved material follow a different internal procedure with respect to the standard material.

Note No. 3 : the present declaration It is not valid unless accompanied by a certificate showing the identification (Lot No.) of material supplied