

# Chemelot Campus eLetter

For everyone working or studying on Chemelot Campus

## Interface BIOMaterials acquires ISO and CE qualifications

### ISO 13485 certificate en CE marking

Interface BIOMaterials B.V. (INBIO), located in the Van Iterson Building at Chemelot Campus, is a young company servicing the biomedical industry. Recently, this spin-off of the Maastricht University has acquired an ISO 13485 certificate for its quality management system as well as a CE marking for its newest innovation, X-Spheres™.

EN ISO 13485 : 2010 represents the requirements of a comprehensive quality management system for the design, development, manufacture and distribution of **medical devices**. INBIO needs a **CE marking** for the commercialization of X-Spheres™ throughout Europe.



Since it's very complicated to acquire both qualifications, in particular for a young and small company, we congratulate Interface BIOMaterials with this excellent performance!

### Collaboration

Says Leo Koole, CEO of INBIO and professor at the Maastricht University (Department of Biomedical Engineering): "To acquire these qualifications we have worked closely with several parties. One of these is our neighbor Basic Pharma B.V., a pharmaceutical company, also located in the Van Iterson Building - conveniently nearby." Other partners include Rembrandt Medical B.V. (Eemnes), and the universities of Maastricht, Aachen (RWTH and Fachhochschule), Liege, and Hasselt.

### Innovation in uterine artery embolization: X-Spheres™

INBIO's innovation is an improvement of a medical device that is already in use for many years to treat uterine fibroids. These are benign tumors in the human uterus that cause pain and other complaints. The typical treatment of the disease is surgery to remove the fibroid or even the whole uterus (hysterectomy).

Often a more elegant (and cheaper) treatment can be used (and is actually preferred): **uterine artery embolization** (UAE). UAE is a modern minimal invasive approach, a catheter-based technique. Via the artery a liquid with microspheres (very tiny beads) is brought into the fibroid with the arterial blood. These particles clog the artery system in the tumor and as a result the fibroid shrinks and the symptoms disappear. This type of treatment has a relatively high patient satisfaction: compared to hysterectomy hospital stay, duration of recovery and time off work are shorter.

The innovation of INBIO in X-Spheres™ does not concern the UAE treatment™ as such, but an additional feature to better guide the microspheres into the fibroid. The microspheres have been treated in such a way that they are **radio-opaque**: the particles absorb X-radiation. The microspheres can be visualized with X-ray fluoroscopy, a technique typically used to perform the UAE treatment. As a result, the microspheres can be watched while leaving the catheter and entering the artery system of the fibroid. This makes it easier for the physician to perform the UAE treatment in an effective and safe way: insert the microspheres where they are needed.

Currently, the X-Spheres™ product is still subject to post-market clinical evaluation studies.



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