

The management system of

# ALTIMED JSC

5 Dimitrova Str., Minsk, 220004, Republic of Belarus

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 1 April 2014 until 23 March 2017 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 24 January 2015  
Issue 7. Certified since 24 March 2009

Certification is based on reports numbered PL/WAW-PL00460

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

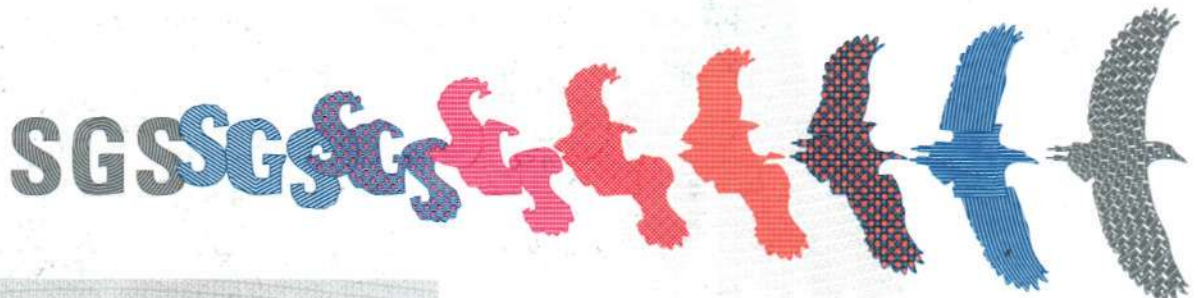
Authorised by

**SGS United Kingdom Ltd, Notified Body 0120**

SGS United Kingdom Ltd Systems & Services Certification  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311 M2

Page 1 of 2



## **ALTIMED JSC**

### **Directive 93/42/EEC**

on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

**Sterile Cemented Femoral Hip Stem.**

**Sterile SLPS Cementless Femoral Hip Stem.**

**Sterile Cemented Acetabular Cup.**

**Sterile Alumina (BioloX) Modular Ceramic Femoral Heads.**

**Cobalt-Chrome-Molybdenum Alloy Modular Femoral Heads.**

**Threaded and press-fit cementless acetabular cup shells.**

**Ultra-highMolecular Weight Polyethylene bearing inserts.**

**Ultra-high Molecular Weight Polyethylene inserts with Alumina  
ceramic bearing surfaces.**

**Alumina Ceramic bearing inserts.**

**Austin Moore Endoprosthesis: Sterile femoral heads for partial hip  
joint replacement systems.**

**Sterile partial Hip implants including Centralizer, Protrusion ring and  
Cancellous screws.**

**Non sterile Osteosynthesis implants including screws, plates, wires  
and pins.**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination  
Certificate according to Annex II (Section 4) is required.

Additional facilities

**Proektiruemaya 2a, Osipovichi, Mogilev Oblast, 213760,  
Republic of Belarus**