



My Commission Expires: January 22, 2018



Bioventus LLC  
4721 Emperor Blvd., Suite 100  
Durham, NC 27703  
USA

1-919-474-6700  
1-800-396-4325  
www.BioventusGlobal.com

## DECLARATION OF CONFORMITY

**PRODUCT NAME:** *Durolane<sup>®</sup> and Durolane<sup>®</sup> SJ (small joints)*

**PART NUMBERS:** 10-82004, 10-82010, 10-82011, 10-82012, 10-82013, 10-82014, 10-82018, 10-81105, 10-82015

**CLASSIFICATION:** Class III

**RULE:** Annex IX, Rule 8, Indent 3

This is to certify that the above mentioned products meet the applicable provisions of the EC Medical Devices Directive (93/42/EEC as amended by 2007/47/EC), which entitles them to bear the **CE0086** marking. The applicable provisions are Annex II and Annex II.4.

**Approval:**

  
\_\_\_\_\_  
Director of Regulatory Affairs or Designee

\_\_\_\_\_  
Date 11/8/12

**Manufacturer's Name:** Bioventus LLC  
**Manufacturer's Address:** 4721 Emperor Boulevard, Suite 100  
Durham 27703, North Carolina

**Manufacturing Site(s)/ Addresses:** Q-Med AB  
Seminariégatan 21  
SE-752 28 Uppsala, Sweden

**EC Representative's Name:** Emergo Europe  
**EC Representative's Address:** Molenstraat 15  
2513 BH, The Hague  
The Netherlands

**Notified Body's Name:** BSi Healthcare  
**Notified Body's Address:** Davy Avenue  
Milton Keynes  
MK5 8PP, UK