

**DECLARATION OF CONFORMITY**

**MANUFACTURER:** Arriol International Corp.  
Zona Franca San Isidro  
Carretera San Isidro Km. 17  
Santo Domingo, Dominican Republic

**EU AUTHORIZED REPRESENTATIVE:** Maria Luberkis Arias R.  
Rua Francisco Largo Caballero 7D, Piso 4H  
O Burgo, Culleredo  
A Coruña 15670, Spain

**PRODUCT:** B-CLAMP  
Part No. ABT120001

**CLASSIFICATION:** Class IIb

We herewith declare that the above mentioned product meets the provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure of Annex II, is executed by the manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the certification notice and retained under the premises of the manufacturer.

This declaration is supported by the Quality System Certification based on the Harmonized Standards ISO 13485:2003, Quality System Certificate with Reference Number: 560213 Issued on September 10, 2002 / Renewed on September 10, 2017 and delivered by DEKRA CERTIFICATION B.V.

**NOTIFIED BODY:** DEKRA Certification B.V.  
Meander 1051, 6825 MJ Arnhem  
P.O. Box 5185, 6802 ED Arnhem  
The Netherlands  
I.D. No.: 0344

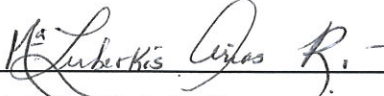
**EC CERTIFICATION NUMBER:** 3806603CE01

**TIME RELATED INFORMATION:** Issued May 16, 2016  
Reissued September 10, 2017

**PLACE, DATE OF ISSUE:** Santo Domingo, September 25, 2017

**SIGNATURES:**

  
\_\_\_\_\_  
Sabina Monegro  
Quality Assurance and Regulatory Assurance Manager

  
\_\_\_\_\_  
Maria Luberkis Arias R.  
EU Authorized Representative