



Declaration of Conformity

Manufacturer
Address

Balt USA, LLC
29 Parker
Irvine, CA 92618
USA

European
Representative

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Product

Ballast 088 Long Sheath

Model Number
BALLAST80
BALLAST90
BALLAST100
BALLAST105

Classification (MDD, Annex IX): Rule 7 subclause 2 - Class III

We herewith declare under our sole responsibility according to Directive 93/42/EEC Annex II (with 4.) that as of the date of this declaration, the abovementioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer and the notified body.

Directive

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993 concerning Medical Devices

Standards:

Harmonized Standards (published in the Official Journal of the European Communities)
applicable to this product are referenced in TF-0015.

Notified Body:

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
DE-60433 Frankfurt am Main
Germany
Reg. #: 0297

Certificate: 541963 MRA
Valid Until: 11/28/2023
Date CE mark was affixed: 11/29/2018
Place, Date: Irvine, CA, USA 28/03/2022

Signed


Analia Staubly, Director of Regulatory Affairs