balt	***CE DECLARATION OF CONFORMITY*** ***HYBRID*** ***Hydrophilic guidewire***	**DCE-04 rev.4.01** Page 1 of 2

Manufacturer	BALT Extrusion SAS
Address	10 rue de la Croix Vigneron 95160 Montmorency France
Product	**HYBRID** **(See detailed references on page 2)** GMDN code: 35094 - Cardiac catheter guidewire, single use.

Classification (MDD, Annex IX): Rule 6 Class III
We herewith declare in sole responsibility that as of the date of this declaration, the above mentioned 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 (MDD 93/42/EEC), Rule 6 per Annex IX of the MDD

Standards:
Harmonized Standards (published in the Official Journal of the European Communities) applicable to these products can be referenced in TF-18 Section 3-4.

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

Annex II section 3 :	CE Certificate n° 513975 MR2
Valid Until:	26 May 2024
Annex II section 4 :	CE Certificate n°536983 MRA
Valid Until:	26 May 2024
Place, Date	Montmorency, France, 06 February 2020

Signed

Sophie Réhault, Quality and Regulatory Affairs Director - Management Representative

Digitally signed by Voronțov Alexei
Date: 2024.11.14 09:16:49 EET
Reason: MoldSign Signature
Location: Moldova
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