

## MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 162783-2014-AQ-ITA-ACCREDIA

Initial certification date: 01 July 2008

Valid: 22 July 2022 – 21 July 2025

This is to certify that the management system of

## Resonetics LLC- HQ & Operation Unit

3 Berkshire Boulevard, Bethel, CT, 06801-1037, USA

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Third party production of nickel-titanium (Nitinol) wire, strip, tube, prototype development, advanced laser processing, shape forming, specialized micro-coiling, EDM, grinding, hydrophilic coating and chemical processing for medical applications.

Third party production of Stainless Steel micro-coiling for medical applications

Place and date: Vimercate (MB), 10 April 2024





SGQ N° 003 A SGA N° 003 D SGE N° 007 M

PRD N° 003 B PRS N° 094 C SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA ILAC per gli schemi di accreditamento IAB MED I AT For the issuing office: DNV - Business Assurance Via Energy Park, 14, - 20871 Vimercate (MB) -

Maudie Bownund

Claudia Baroncini Management Representative



Certificate no.: 162783-2014-AQ-ITA-ACCREDIA Place and date: Vimercate (MB), 10 April 2024

## **Appendix to Certificate**

## Resonetics LLC- HQ & Operation Unit

Locations included in the certification are as follows:

| Site Name                           | Site Address   | Site Scope  |
|-------------------------------------|--|---|
| Resonetics LLC- HQ & Operation Unit | 3 Berkshire Boulevard, Bethel, CT, 06801-<br>1037, USA | Third party production of nickel-titanium (Nitinol) wire, strip, tube, prototype development, advanced laser processing, shape forming, specialized micro-coiling, EDM, grinding, hydrophilic coating and chemical processing for medical applications.  Third party production of Stainless Steel micro-coiling. |
| Resonetics LLC - Operation Unit     | 8 Berkshire Boulevard, Bethel, CT, 06801-<br>1037, USA | Third party production of nickel-titanium (Nitinol) wire, strip, assembly, laser welding, specialized micro-coiling for medical applications. Third party production of Stainless Steel micro-coiling.  |
| Resonetics LLC - Operation Unit     | 4065 Campbell Avenue, Menlo Park, CA, 94025, USA       | Third party production of nickel-titanium (Nitinol) wire and tube for medical applications.   |
| Resonetics LLC - Operation Unit     | 15 Berkshire Boulevard, Bethel, CT, 06801-1037, USA    | Testing and analysis of nickel-titanium (Nitinol) wire, strip, tube, sheet and components for medical applications.   |
| Resonetics LLC - Operation Unit     | 6 Research Drive, Bethel, CT, 06801, USA               | Third party production of nickel-titanium (Nitinol) tube, EDM and grinding for medical applications.  |