



Electropolishing Systems, Inc.

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ISO 9001
ISO 13485

$\frac{\text{CONTROL}}{\text{PROCESS}} = \text{Quality}$

07/09/10

To whom it may concern,

Electropolishing Systems Inc. has conducted a thorough review and validation of our cleaning, passivation, electropolishing and anodizing processes. These processes were validated to determine their performance against Cytotoxicity, Bioburden, Endotoxicity, and Particulate Accumulation testing. Documentation for these studies includes among others ESI IQ PVAI02813, ESI OQ PVAI 02813 and ESI PQ PVAI 02813. Since your components are processed through equivalent cleaning, passivation, electropolishing and anodizing processes, ESI Inc. has provided you with the results of these tests as proof of validation. As you can see from the following test results, these processes effectively produce clean and contaminant free surfaces on your products. Finally, the redacted areas of the provided reports relate only to proprietary information.

Please note that although the testing specified here was completed on Stainless Steel specimens, the same processes and procedures apply for Titanium and Cobalt Chromium.

Sincerely,
Thomas Hatch
General Manager
ESI Inc.

Validation Date: 06/2010
Test Date: 06/25/2010, 6/28/2010, 7/01/2010, 7/06/2010
Sample #'s (534185 Particle Counts), (534182 Endotoxicity), (534376534386534391 534395 534397 Cytotoxicity), (534370534387 534394 534392 534396 Bioburden)