

Valentin-Rodriguez, Celimar

From: Craig Reed <creed@teambest.com>
Sent: Thursday, October 30, 2014 6:02 PM
To: Herrera, Tomas
Cc: Ruth Bergin
Subject: Novoste Beta-Cath System GA-1115-D-101-S Nameplate
Attachments: Novoste Transfer Device Bottom Images.pdf; TD Bottom Scan.pdf

To Mr. Tomas Herrera, USNRC HQ

In reference to our telephone conversation of Oct. 30, 2014 regarding SS&D Registration Certificate number GA-1115-D-101-S and specifically, "Figure 9. Sample Labeling, bottom of the transfer device" - current photos showing the transfer device bottom with nameplate (against a 1"x1" grid, a 1cm x 1cm grid and no grid) are attached in two pdf files.

All transfer devices were originally manufactured by Novoste Corporation. Service that occurred after a switch in Notified Body from TUV to BSI prompted a CE mark symbol change replacing "0123" with "0086." (The switch in Notified Body did not involve any design change or modification to the product.) New nameplates applied by *Best Vascular, Inc.* during service reflect "0086" as well as "Manufactured by: **Best Vascular, Inc.**"

Other international symbols on the nameplate may be updated when necessary. For example, I expect the old style *General Warning* symbol (triangle with exclamation mark) could be replaced with the newer *Refer to instruction manual/booklet* symbol (person holding a book) when the nameplate is next updated for international use.

Lastly, Best Vascular, Inc. owns and continues to use the "Novoste" and "Novoste Beta-Cath 3.5F System" name brands and associated trademarks. For accuracy, the SS&D registration certificate and associated USNRC licensing guidance can reflect that the Novoste Beta-Cath 3.5F System is manufactured and distributed by Best Vascular, Inc.

We currently distribute the Model A1767 Transfer Device, however, our US FDA PMA continues to authorize marketing of Models A1730, A1732 and A1733, which together with the A1767 form the "A1000 Series."

Kind regards,

Craig Reed
Director, Radiation Science & RSO
Best Vascular, Inc.