

Aug 2, 2020

Dear Tecomet Kenosha,

We are requesting your support in relation to a change in the labelling requirements for medical devices. This will apply to stainless steel alloy materials that you purchase for manufacturing of Wright Medical Products.

Upon new MDR requirements cobalt metal is affected by a harmonized classification procedure in CMR (Carcinogenic, Mutagenic or Toxic for Reproduction) type 1B in the CLP Regulation (EC Regulation No. 1272/2008 on the classification, labeling and labeling of packaging of substances and mixtures). EU REACH Regulation has adopted a limit of CMR substances in the raw material of <0.1% w/w to better protect human health and the environment against the risks associated with these chemicals.

New ASTM/ISO standard updates have been made to assist in the identification of cobalt in stainless steel alloys. ASTM F138 and ISO 5832-9 have been updated to require that cobalt is <0.1% w/w in 316L and M30NW stainless steels respectfully. Additionally, ASTM F899 has been updated to ensure that cobalt concentrations are documented for 300 and 400 series stainless steels, however the limit is not controlled.

We are requesting your assistance in ensuring that your raw material suppliers are providing documentation that are compliant with these new updates. We have reviewed batch records of our products that you have manufactured and have identified the at risk materials and raw material suppliers in the second page of this letter. Can you please complete the following requests?

- Can you verify the accuracy and completeness of the spreadsheet of stainless steel grades and raw material suppliers you purchase this material from?
- Can you provide one example of each raw material cert for each material/raw material supplier pair? The most recent order would be preferred to ensure new ASTM standard requirements are being met.
- Can you confirm if any work has taken place with the identified raw material suppliers to see if they are able to control raw materials to <0.1% w/w for ASTM F899 stainless steels as well as for other grades that do not fall in the 300 and 400 series of stainless steels. If yes, could you please answer the questions in the supplemental questions attachment.

Best regards,

Cameron Moore

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Please Notify Wright Medical if there are any discrepancies

Material	Material Standard	Raw Material Supplier	Co Mentioned
13-8 SS	ASTM A564 Type XM-13	Banner Service Corp	<0.05
17-4 SS	ASTM A564 Type 630	Tri Star Metals	0.11
17-4 SS	ASTM A564 Type 630	Carpenter	No
17-4 SS	ASTM A564 Type 630	Boston Centerless	No
17-4 SS	ASTM A564 Type 630	Earle M. Jorgensen Company	No
18-8 SS			
302 SS	ASTM A276 Type 302	Inner Mongolia Jining Litai Welding & Metalco	No
303 SS	ASTM A582 Type 303	Round Ground Metals	0.15
303 SS	ASTM A582 Type 303	Copper and Brass Sales	0.165
303 SS	ASTM A582 Type 303	Manz Edelstahl	No, listed as N/A
304 SS	ASTM A276 Type 304	SWS Edelstahl GmbH	No
316 SS	ASTM A276 Type 316	Manz Edelstahl	No, listed as N/A
420 SS	ASTM A276	Chirurgische Instrumente	Not mentioned

Material	Material Standard	Raw Material Supplier	Co Mentioned
440C SS	ASTM A276 Type 440C		
455 SS	ASTM A564 Type XM-16	United Performance Metals	No
Stainless Steel			
Viton	ASTM D1418		

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