

Terumo Europe N.V.

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Subject: Notification of Code addition – Radifocus Optitorque

Dear,

With this letter we would like to inform you that to ensure business continuity of our Radifocus Optitorque, additional codes manufactured in TC – Ashitaka Factory and Terumo Vietnam Corporation will be available.

As these codes are already in scope of the current Declaration of Conformity's item code matrix, there is no update on the applicable documents.

In Annex I you will find the full list of codes manufactured by both TC – Ashitaka Factory and Terumo Vietnam Corporation.

Please note: Not all codes might be available for order in your Country/Region, for any specific questions on codes availability please contact the Product Manager.

Regarding this code addition, we would like to ask your support to perform the necessary actions in your country(ies). In case additional documents might be needed please share the list with us by mail.

Thank you for taking the time to take the necessary actions, and for sharing with us the confirmation once the actions are completed.

Should you need more information, please do not hesitate to contact me.

Thank you in advance

Best regards,

A handwritten signature in black ink, appearing to be "V".

Valeria Piattelli
Regulatory Affairs Specialist
Terumo Europe N.V.

Annex I– List of codes.

Item codes manufactured in Terumo Corporation – Ashitaka Factory

1.	RH*4AL1000M
2.	RH*4AP4561M
3.	RH*4APR241M
4.	RH*4BL3520M
5.	RH*4BL3521M
6.	RH*4BL3522M
7.	RH*4BL4020M
8.	RH*4BL4021M
9.	RH*4BL4022M
10.	RH*4BPIN00M
11.	RH*4CL3500M
12.	RH*4CL4000M
13.	RH*4CR3500M
14.	RH*4CR4000M
15.	RH*4JL3500M
16.	RH*4JL4000M
17.	RH*4JR3500M
18.	RH*4JR4000M
19.	RH*4MP2520M
20.	RH*4MP2528M
21.	RH*4MP3020M
22.	RH*4MP3028M
23.	RH*4MP4020M
24.	RH*4PR2008M
25.	RH*4PR2508M
26.	RH*4SP0061M
27.	RH*4SP0068M
28.	RH*5AL1000M
29.	RH*5AL2000M
30.	RH*5AL3000M
31.	RH*5AP4561M
32.	RH*5AP5561M
33.	RH*5APR241M
34.	RH*5AR1000M
35.	RH*5AR2000M
36.	RH*5AR3000M
37.	RH*5BL3520M
38.	RH*5BL3521M
39.	RH*5BL3522M
40.	RH*5BL4021M

41.	RH*5BL4022M
42.	RH*5BPIN00M
43.	RH*5BPIR00M
44.	RH*5BPJL00M
45.	RH*5BPJR00M
46.	RH*5CAS100M
47.	RH*5CL3500M
48.	RH*5CL4000M
49.	RH*5CL5000M
50.	RH*5CL6000M
51.	RH*5CR3500M
52.	RH*5CR3528M
53.	RH*5CR4000M
54.	RH*5CR5000M
55.	RH*5JL3500M
56.	RH*5JL4000M
57.	RH*5JL5000M
58.	RH*5JR3500M
59.	RH*5JR4000M
60.	RH*5JR5000M
61.	RH*5JR6000M
62.	RH*5MP2520M
63.	RH*5MP2528M
64.	RH*5MP3020M
65.	RH*5MP3520M
66.	RH*5MP352NM
67.	RH*5MP4020M
68.	RH*5SP0061M
69.	RH*5SP0062M
70.	RH*5SP0068M
71.	RH*5TIG110M
72.	RH*5TIG210M
73.	RH*6AL1000M
74.	RH*6AL2000M
75.	RH*6AL3000M
76.	RH*6AP4561M
77.	RH*6AP5561M
78.	RH*6AR1000M
79.	RH*6AR2000M
80.	RH*6AR3000M
81.	RH*6BL3520M
82.	RH*6BL4020M
83.	RH*6BPIN00M

84.	RH*6BPIR00M
85.	RH*6BPJL00M
86.	RH*6BPJR00M
87.	RH*6CL3500M
88.	RH*6CL4000M
89.	RH*6CL5000M
90.	RH*6CL6000M
91.	RH*6CR3500M
92.	RH*6CR4000M
93.	RH*6CR5000M
94.	RH*6JL3500M
95.	RH*6JL4000M
96.	RH*6JL5000M
97.	RH*6JR3500M
98.	RH*6JR4000M
99.	RH*6JR5000M
100.	RH*6JR6000M
101.	RH*6MP2520M
102.	RH*6MP3020M
103.	RH*6MP3520M
104.	RH*6MP4020M
105.	RH*6RD3000M
106.	RH*6SP0061M
107.	RH*6TIG110M
108.	RH*6TIG210M
109.	RH*6TR4000M
110.	RH*AB44108M
111.	RH*AB4410GM
112.	RH*AB54108M
113.	RH*AB5410GM
114.	RH*AB64108M
115.	RH*AC4410GM
116.	RH*AD44108M
117.	RH*AD4410GM
118.	RH*AD6410GM
119.	RH*AG34108M
120.	RH*AG94107M
121.	RH*AGF4108M
122.	RH*AB45108M
123.	RH*AB4510GM
124.	RH*AB55108M
125.	RH*AB5510GM
126.	RH*AB65108M

127.	RH*AG95107M
128.	RH*BA14110M
129.	RH*BA24110M
130.	RH*BA34110M
131.	RH*BB14110M
132.	RH*BE14110M
133.	RH*BE24110M
134.	RH*BH14110M
135.	RH*BA15110M
136.	RH*BA25110M
137.	RH*BA2511CM
138.	RH*BA35110M
139.	RH*BB15110M
140.	RH*BB25110M
141.	RH*BE15110M
142.	RH*BE25110M
143.	RH*BE25112M
144.	RH*BH15110M
145.	RH*BH1511CM
146.	RH*BH15112M

Item codes manufactured in Terumo Vietnam Corporation

1.	RH*4AL1000M
2.	RH*4AL2000M
3.	RH*4AL3000M
4.	RH*4AP4561M
5.	RH*4AP5561M
6.	RH*4APR241M
7.	RH*4AR1000M
8.	RH*4AR2000M
9.	RH*4ARJP00M
10.	RH*4BPIN00M
11.	RH*4BPJP00M
12.	RH*4CL3500M
13.	RH*4CL4000M
14.	RH*4CL5000M
15.	RH*4CR3500M
16.	RH*4CR4000M
17.	RH*4CR5000M
18.	RH*4JL3500M
19.	RH*4JL4000M

20.	RH*4JR3500M
21.	RH*4JR4000M
22.	RH*4MP2520M
23.	RH*4MP2528M
24.	RH*4MP3020M
25.	RH*4MP3028M
26.	RH*4MP3520M
27.	RH*4MP3521M
28.	RH*4MP4020M
29.	RH*4PR2008M
30.	RH*4PR2508M
31.	RH*4SP0061M
32.	RH*4SP0068M
33.	RH*4SP0069M
34.	RH*4SP006GM
35.	RH*4ST0109M
36.	RH*4ST0161M
37.	RH*4ST016GM
38.	RH*5AL1000M
39.	RH*5AL2000M
40.	RH*5AL3000M
41.	RH*5AP4561M
42.	RH*5AP5561M
43.	RH*5APR241M
44.	RH*5AR1000M
45.	RH*5AR2000M
46.	RH*5AR3000M
47.	RH*5ARJP00M
48.	RH*5BL3520M
49.	RH*5BL4020M
50.	RH*5BLK410M
51.	RH*5BLK411M
52.	RH*5BPIM00M
53.	RH*5BPIN00M
54.	RH*5BPIR00M
55.	RH*5BPJL00M
56.	RH*5BPJP00M
57.	RH*5BPJR00M
58.	RH*5BPRB01M
59.	RH*5BU3500M
60.	RH*5CAS100M
61.	RH*5CL3500M
62.	RH*5CL4000M

63.	RH*5CL4001M
64.	RH*5CL4500M
65.	RH*5CL5000M
66.	RH*5CL5001M
67.	RH*5CL6000M
68.	RH*5CL6001M
69.	RH*5CR3500M
70.	RH*5CR3521M
71.	RH*5CR3528M
72.	RH*5CR4000M
73.	RH*5CR4001M
74.	RH*5CR4500M
75.	RH*5CR5000M
76.	RH*5FJ1000M
77.	RH*5JL3500M
78.	RH*5JL4000M
79.	RH*5JL5000M
80.	RH*5JR3500M
81.	RH*5JR4000M
82.	RH*5JR5000M
83.	RH*5JR6000M
84.	RH*5MP2520M
85.	RH*5MP2528M
86.	RH*5MP3020M
87.	RH*5MP3500M
88.	RH*5MP3520M
89.	RH*5MP4001M
90.	RH*5MP4020M
91.	RH*5SP0061M
92.	RH*5SP0068M
93.	RH*5SP006GM
94.	RH*5TIG110M
95.	RH*5TIG111M
96.	RH*5TR3510M
97.	RH*5TR4000M
98.	RH*5TR4001M
99.	RH*5TR4010M
100.	RH*5TR4500M
101.	RH*5TR5000M
102.	RH*5TR5001M
103.	RH*6AL1000M
104.	RH*6AL2000M
105.	RH*6AL3000M

106.	RH*6AP4561M
107.	RH*6AP5561M
108.	RH*6APR241M
109.	RH*6AR1000M
110.	RH*6AR2000M
111.	RH*6AR3000M
112.	RH*6ARJP00M
113.	RH*6BLK410M
114.	RH*6BPIN00M
115.	RH*6BPIR00M
116.	RH*6BPJL00M
117.	RH*6BPJR00M
118.	RH*6CL3500M
119.	RH*6CL4000M
120.	RH*6CL4020M
121.	RH*6CL4500M
122.	RH*6CL5000M
123.	RH*6CL6000M
124.	RH*6CR3500M
125.	RH*6CR4000M
126.	RH*6CR4020M
127.	RH*6CR4500M
128.	RH*6CR5000M
129.	RH*6CR6000M
130.	RH*6JL3500M
131.	RH*6JL4000M
132.	RH*6JL5000M
133.	RH*6JR3500M
134.	RH*6JR4000M
135.	RH*6JR5000M
136.	RH*6JR6000M
137.	RH*6MP2520M
138.	RH*6MP3020M
139.	RH*6MP3500M
140.	RH*6MP3520M
141.	RH*6MP4020M
142.	RH*6SP0061M
143.	RH*6TIG110M
144.	RH*6TR3500M
145.	RH*6TR4000M
146.	RH*6TR5000M
147.	RH*AB44108M
148.	RH*AB4410GM

149.	RH*AB45108M
150.	RH*AB4510GM
151.	RH*AB54108M
152.	RH*AB5410GM
153.	RH*AB55108M
154.	RH*AB5510GM
155.	RH*AB64108M
156.	RH*AB65108M
157.	RH*AC3510GM
158.	RH*AC4410GM
159.	RH*AC4510GM
160.	RH*AD44108M
161.	RH*AD4410GM
162.	RH*AD5410GM
163.	RH*AD5510GM
164.	RH*AD6410GM
165.	RH*AD6510GM
166.	RH*AE44108M
167.	RH*AE4410GM
168.	RH*AE4510GM
169.	RH*AE55108M
170.	RH*AED510GM
171.	RH*AF15110M
172.	RH*AG34108M
173.	RH*AG94107M
174.	RH*AG95107M
175.	RH*AGF4108M
176.	RH*AUB5108M
177.	RH*BA14110M
178.	RH*BA15110M
179.	RH*BA24110M
180.	RH*BA34110M
181.	RH*BA35110M
182.	RH*BB14110M
183.	RH*BB15110M
184.	RH*BB24110M
185.	RH*BB25110M
186.	RH*BC14110M
187.	RH*BE14110M
188.	RH*BE15110M
189.	RH*BE24110M
190.	RH*BE25110M
191.	RH*BG14110M

192.	RH*BH14110M
193.	RH*BH15110M
194.	RH+4AL3000M
195.	RH+4ARJP00M
196.	RH+4BPJP00M
197.	RH+4CL5000M
198.	RH+4CR5000M
199.	RH+4MP2528M
200.	RH+4MP3520M
201.	RH+4SP006GM
202.	RH+4ST0161M
203.	RH+4ST016GM
204.	RH+5ARJP00M
205.	RH+5BL3520M
206.	RH+5BL4020M
207.	RH+5BLK410M
208.	RH+5BLK411M
209.	RH+5BPIM00M
210.	RH+5BPJP00M
211.	RH+5BPRB01M
212.	RH+5BU3500M
213.	RH+5CL4001M
214.	RH+5CL4500M
215.	RH+5CL5001M
216.	RH+5CL6001M
217.	RH+5CR3521M
218.	RH+5CR4001M
219.	RH+5CR4500M
220.	RH+5MP3500M
221.	RH+5MP4001M
222.	RH+5TIG111M
223.	RH+5TR3510M
224.	RH+5TR4000M
225.	RH+5TR4001M
226.	RH+5TR4010M
227.	RH+5TR4500M
228.	RH+5TR5000M
229.	RH+5TR5001M
230.	RH+6ARJP00M
231.	RH+6BLK410M
232.	RH+6CL4020M
233.	RH+6CL4500M
234.	RH+6CR4020M

235.	RH+6CR4500M
236.	RH+6CR6000M
237.	RH+6MP3500M
238.	RH+6TIG110M
239.	RH+6TR3500M
240.	RH+6TR5000M
241.	RH+AC4510GM
242.	RH+AD5510GM
243.	RH+AE44108M
244.	RH+AE4410GM
245.	RH+AE4510GM
246.	RH+AE55108M
247.	RH+AED510GM
248.	RH+AF15110M
249.	RH+AUB5108M
250.	RH+BC14110M
251.	RH+BG14110M

If you feel we have missed something important, please come back to us as soon as possible.