

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE Regulation 2016/425</b> <b>RECOMMENDATION FOR USE</b>	PPE-R/08.060 Revision 01 Language: E																																																
Number of pages: 1	Approval stage:	Approved on:																																																
Origin: VG8	<input checked="" type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input type="checkbox"/> EU PPE Expert Group	(31.08.2023) (30.09.2024) (date)																																																
Question related to	<input type="checkbox"/> PPE Regulation	<input checked="" type="checkbox"/> EN/prEN:																																																
EN 13138-1:2021	Clause 8.2	<input type="checkbox"/> Other:																																																
EN 13138-3:2021	Clause 5.8																																																	
Key words: Human Subject testing; Manikin testing																																																		
Question:  The prescribed Manikins in EN 13138:2021 series of standards represent a constraint on the testing laboratories involved with the testing of swim aids. The use of Infants and Children human test subjects is still permitted for human subject testing for Buoyancy Aids and Lifejackets in the EN ISO 12402:2020 series of standards, in which the testing is arguably more arduous.  Is it possible to conduct the In-Water testing prescribed in Clauses 8.2 of EN 13138-1:2021 and <del>Clause 5.8 of EN 13138-3:2021</del> using Human Subjects rather than the prescribed Manikins in Annex B? If so, what is the selection criteria for Human Subjects?																																																		
Solution:  Yes, human subjects may be used in lieu of manikins for the testing prescribed in EN 13138- <del>1</del> :2021. The testing is to be conducted under strict supervision of lifeguards and parents and appropriate allowances in the testing made to keep the subject safe.  The user mass of the manikins for the relevant age groups stated in EN 13138-1:2021 & <del>EN 13138-3:2021</del> shall be used for test subject selection criteria with a minimum of one test subject tested in each size criteria appropriate to the swim aid as follows:																																																		
<table><tr><th colspan="3">EN 13138-1:2021 Table 4</th><th colspan="3"><del>EN 13138-3:2021 Table 1</del></th></tr><tr><th>Age years</th><th>User Mass Range (kg)</th><th>Human Subjects to be tested</th><th><del>Age years</del></th><th><del>User Mass</del></th><th><del>Human Subjects to be tested</del></th></tr><tr><td>≤ 1</td><td>≤ 11</td><td>One subject ≤11kg</td><td><del>≤ 1</del></td><td><del>≤ 11kg</del></td><td><del>One subject ≤11kg</del></td></tr><tr><td>1 to 2</td><td>&gt; 11 - 15</td><td>One subject &gt;11-15kg</td><td><del>&gt; 1 to 2</del></td><td><del>&gt; 11kg to 15kg</del></td><td><del>One subject &gt;11-15kg</del></td></tr><tr><td>2 to 3</td><td>&gt; 15 - 19</td><td>One subject &gt;15-19kg</td><td><del>&gt; 2 to 3</del></td><td><del>&gt; 15kg to 19 kg</del></td><td><del>One subject &gt;15-19kg</del></td></tr><tr><td>3 to 6</td><td>19 - 30</td><td>One subject at the low end &gt;19-25kg One subject at the high end &gt;25-30kg</td><td></td><td></td><td></td></tr><tr><td>6 to 12</td><td>30 - 60</td><td>One subject at the low end &gt;30-40kg One subject at the high end &gt;50-60kg</td><td></td><td></td><td></td></tr><tr><td>&gt;12</td><td>60 - 80</td><td>One subject at the low end &gt;60-70kg One subject at the high end &gt;70-80kg</td><td></td><td></td><td></td></tr></table>			EN 13138-1:2021 Table 4			<del>EN 13138-3:2021 Table 1</del>			Age years	User Mass Range (kg)	Human Subjects to be tested	<del>Age years</del>	<del>User Mass</del>	<del>Human Subjects to be tested</del>	≤ 1	≤ 11	One subject ≤11kg	<del>≤ 1</del>	<del>≤ 11kg</del>	<del>One subject ≤11kg</del>	1 to 2	> 11 - 15	One subject >11-15kg	<del>&gt; 1 to 2</del>	<del>&gt; 11kg to 15kg</del>	<del>One subject &gt;11-15kg</del>	2 to 3	> 15 - 19	One subject >15-19kg	<del>&gt; 2 to 3</del>	<del>&gt; 15kg to 19 kg</del>	<del>One subject &gt;15-19kg</del>	3 to 6	19 - 30	One subject at the low end >19-25kg One subject at the high end >25-30kg				6 to 12	30 - 60	One subject at the low end >30-40kg One subject at the high end >50-60kg				>12	60 - 80	One subject at the low end >60-70kg One subject at the high end >70-80kg			
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