



**EC – Declaration of Conformity**

We hereby declare that for the products listed below Orfit Industries NV is in compliance with the directive 93/42/EC of the European Community and that it fulfills all the essential and other requirements put forward in the directive with respect to medical devices of class 1.

**Raycast® High Precision  
Base Plate-To-Couch Fixation Devices**

<b>32154</b>	<b>32002</b>	<b>32156</b>	<b>33141</b>	<b>35745</b>
<b>32166</b>	<b>32126</b>	<b>33146</b>	<b>33165</b>	<b>33124</b>
<b>32151</b>	<b>32813</b>	<b>32172</b>	<b>33129</b>	<b>33143</b>
<b>32191</b>	<b>32317/16</b>	<b>32184</b>	<b>32169</b>	<b>33142</b>
<b>32165</b>	<b>32066</b>	<b>32155</b>	<b>32182</b>	<b>33154</b>
<b>32190</b>	<b>33167</b>	<b>32178</b>	<b>32173</b>	<b>33155</b>
<b>35744/6</b>	<b>32822</b>	<b>33134</b>	<b>32174</b>	<b>33156</b>
<b>33109</b>	<b>32045</b>	<b>33159</b>	<b>32185</b>	<b>33166</b>
<b>33119</b>	<b>32810</b>	<b>35154</b>	<b>32179</b>	<b>33144</b>
<b>35747</b>	<b>32160</b>	<b>33133</b>	<b>33148</b>	<b>33145</b>
<b>35747/6</b>	<b>32165/6</b>	<b>33158</b>	<b>33140</b>	<b>33136</b>
<b>32063</b>	<b>32814</b>	<b>33139</b>	<b>33164</b>	<b>32158</b>
<b>35747/4</b>	<b>32815</b>	<b>32157</b>	<b>33138</b>	<b>33126</b>
<b>35747/8</b>	<b>32816</b>	<b>33150</b>	<b>33162</b>	<b>33125</b>
<b>32001</b>	<b>32817</b>	<b>33149</b>	<b>33153</b>	<b>33147</b>
<b>32000</b>	<b>32171</b>	<b>33131</b>	<b>33121</b>	<b>32207</b>
<b>32181</b>	<b>32183</b>	<b>33132</b>	<b>33120</b>	<b>32209</b>
<b>32070/17</b>	<b>32127</b>	<b>33123</b>	<b>33122</b>	<b>33173</b>
	<b>33217</b>	<b>32208</b>	<b>33106</b>	<b>33168</b>

Product description:

Non active, noninvasive medical device class 1.  
Positioning accessories for patient immobilization in radiotherapy.

Applied norms:

Directive 93/42/EC    ISO 13485  
                                  ISO 10993  
                                  ISO 14971

Per annex VII of the Royal Decree of 18/03/1999 for medical devices.

Eddy Marivoet,  
Wijnegem, 9 September 2019

*Quality Assurance & Regulatory Affairs Manager*