

Transition period (Regulation (EU) 2023/1194)



2017 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030

Transitional period CS for products for which: <ul style="list-style-type: none"> • NB involved in conformity assessment • No clinical investigation foreseen 	<ul style="list-style-type: none"> • Product marketed in the EU • Compliant with applicable regulations • No significant changes 	22/06/2023 transition period starts	From 01/01/2027 , signed agreement with NB	From 01/01/2030 , CS compliant
Transitional period CS for products for which: <ul style="list-style-type: none"> • NB involved in conformity assessment • Clinical investigation foreseen 	<ul style="list-style-type: none"> • Product marketed in the EU • Compliant with applicable regulations • No significant changes 	22/06/2023 starts transition period	From 22/06/2024 , positive MDR clinical investigation application From 23/12/2024 , start of clinical investigation	From 01/01/2028 , signed agreement with NB From 01/01/2030 , CS compliant
Transitional period CS for: <ul style="list-style-type: none"> • Lower risk products • Directive 93/42/EEC CE certificate 	<ul style="list-style-type: none"> • Product marketed in the EU • Compliant with applicable regulations • No significant changes • PMS and vigilance MDR compliant 	22/06/2023 starts transition period	From 26/05/2024 , QMS MDR compliant and NB formal application. From 26/09/2024 , signed agreement with NB.	From 01/01/2029 , CS compliant
Transitional period CS for: <ul style="list-style-type: none"> • Higher risk products • Directive 93/42/EEC CE certificate 	<ul style="list-style-type: none"> • Product marketed in the EU • Compliant with applicable regulations • No significant changes • PMS and vigilance MDR compliant 	22/06/2023 starts transition period	From 26/05/2024 , QMS MDR compliant and NB formal application. From 26/09/2024 , signed agreement with NB	From 01/01/2028 , CS compliant

CS: Common Specifications; MDR: Medical Device Regulation (EU) 2017/745; NB: Notified Body; PMS: Postmarket Surveillance; QMS: Quality Management System