1. **Application Type**

Please select the relevant transfer application type.

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| **Transfer of MDR Formal Application**  I want to transfer MDR formal application for MDR devices that are listed in FR.MED.01 Annex 03 from MDR Notified Body to the SZUTEST Konformitätsbewertungsstelle GmbH. |  |
| **Transfer of Appropriate Surveillance of Legacy Devices under the Scope of (EU)2023/607 and (EU) 2023/1194 Regulation**  I want to transfer surveillance assessment(s) of legacy device(s) that are listed in FR.MED.01 Annex 03 from MDR Notified Body to the SZUTEST Konformitätsbewertungsstelle GmbH.  Please also indicate from which surveillance assessment you would like to start transferring the surveillance assessments from the MDR Notified Body to SZUTEST Konformitätsbewertungsstelle GmbH in FR.MED.01 Annex 03. |  |

1. **Required Documents for Application**

Please submit your application including at least the documents listed below.

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| **For Transfer of MDR Formal Application** | **For Transfer of Appropriate Surveillance of Legacy Devices under the Scope of (EU)2023/607 and (EU) 2023/1194 Regulation** |
| • Copies of confirmation letters (if issued)  • Audit reports including their findings lists covering all MDR formal applications being “transferred” (all reports for current certification cycle, including unannounced audit), if applicable  • Technical documentation assessment report(s), and/or list of finding(s) from the assessment, if applicable  • Consultation reports by authorities  • List of open / still pending non-conformities and their grading (minor/major) and related plan of corrections and corrective / preventative actions  • Pending appeals | • Copies of certificate specified in Appendix 1, with any written confirmations to supplement or correct information mentioned in such certificate that covers the legacy devices subject to transfer of appropriate surveillance  • Detailed list(s) of device(s) covered by the certificate  • List of conditions correlated to the certificate(s)  • Prior audit reports including their findings lists – time frame at least current certification cycle  • (AI)MDD full technical documentation(s) of legacy device(s) and the latest related assessment report issued by OUTGOING NB - time frame minimum current certification cycle  • Consultation reports by authorities  • List of vigilance cases – time frame at least current certification cycle  • List of open / still pending non-conformities and their grading (minor/major) and related plan of corrections and corrective / preventative actions  • List of ongoing change notifications being assessed  • Pending appeals |

1. **Reason of Transfer**

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| Please state the reason of transfer in detail. |
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| FR.MED.201 Agreement Related to the Transfer of MDR Formal Application and of Appropriate Surveillance of Legacy Devices will be requested after approval of the application between SZUTEST Konformitätsbewertungsstelle GmbH, Outgoing Notified Body, the applicant and when appropriate surveillance to be transferred, the certification holder. |

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| This form has been filled as the Annex of DD.MM.YYYY dated FR.MED.01 Application Form of the Company. |

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| **Company Representative** | **Name, Surname, Title** | **Signature** | **Date** |
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