Data Protection Impact Assessment (DPIA)

1. General Information

Study Title:	Post Market Clinical Follow-up Study for Long-Term Outcomes for PRECISE PRO Rx
Sponsor (Data Controller):	Cordis US Corp. 14201 Northwest 60th Avenue Miami Lakes, FL 33014, USA
EU Legal Representative (per Art. 27 GDPR):	Cordis Cashel Cahir Road, Cashel Co. Tipperary, Ireland
Study Sites:	Pineta Grande Hospital Via Domiziana km 30/00, 81030 Castel Volturno (CE), Italy Ospedale di Mirano Via Luigi Mariutto 76, 30035 Mirano (VE), Italy IRCCS Policlinico San Donato Piazza Edmondo Malan 2, 20097 San Donato Milanese (MI), Italy
Contract Research Organization: (CRO)	Rede Optimus Hospitalar AG Alte Steinhauserstrasse 1 6330 Cham, Switzerland
Data Protection Officer (DPO):	Dr. Anna Roschek DPO@cordis.com

Note: As the Sponsor is located outside the EU, a legal representative has been appointed in the European Union to act as the contact point for supervisory authorities and data subjects with regard to all issues related to data processing, in accordance with Article 27 GDPR. The Sponsor remains the Data Controller and retains full responsibility for compliance.

2. Description of Processing

This retrospective study involves the collection and analysis of patient data from procedures performed with the PRECISE PRO Rx Nitinol Stent System up to 31 March 2020, with follow-up data up to 5 years. Data will be extracted from medical records at the Italian study sites listed above, pseudonymised by the sites, and entered into an electronic Case Report Form (eCRF). The data set will include demographic information, medical history, procedural details, and clinical outcomes. No directly identifiable data (e.g., names, social security numbers) will be transferred to the Sponsor.

3. Purpose and Legal Basis

The purpose of this study is to evaluate the long-term safety and performance of the PRECISE PRO Rx Nitinol Stent System in real-world clinical practice. The processing of personal data is based on:

- GDPR Article 6(1)(f): Legitimate interests pursued by the controller (scientific research purposes);
- GDPR Article 9(2)(j): Processing necessary for scientific research purposes;
- Compliance with the guidelines of GPDP for retrospective studies, identified by *Art. 106, paragraph 2, letter d)* of Italian Privacy Code, as indicated in the "Regole deontologiche" referred to *artt. 2-quater and 106* of Italian Privacy Code.

4. Necessity and Proportionality

The processing is limited to what is necessary for the scientific objectives of the study. Only pseudonymised data will be collected. Access is restricted to authorized study personnel, and data will be retained only for the duration necessary to achieve the research objectives and comply with regulatory requirements.

5. Risk Assessment

The primary risks relate to the potential re-identification of pseudonymised patient data, unauthorized access, data breaches, or misuse. As the data concerns health information of patients (a vulnerable group), the risk level is considered high without mitigation measures.

6. Measures to Address Risks

To mitigate risks, the following measures are implemented:

- Pseudonymisation of all patient data before entry into the eCRF;
- Secure access controls (role-based, password-protected systems);
- Encryption of data in transit and at rest;
- Data minimisation (only study-relevant variables collected);
- Limited retention periods in line with GPDP and GDPR requirements;

- Staff training in data protection and confidentiality.

For international data transfers, a Data Processing Agreement (DPA) has been executed between the Sponsor and the CRO, incorporating EU Standard Contractual Clauses (SCCs) to ensure adequate safeguards for transfers to the United States.

7. Involvement of DPO and Stakeholders

The Sponsor's Data Protection Officer (DPO) has reviewed this DPIA and provided input on risk assessment and mitigation measures. The CRO and Italian study sites, listed above, are involved in ensuring proper data handling. The views of data subjects were not directly sought, as this is a retrospective study using existing medical records.

8. Residual Risk and Consultation with GPDP

After applying the above safeguards, the residual risk to patient data is considered low. Consultation with the Italian Data Protection Authority (GDPD) is not deemed necessary unless significant changes to processing occur or new risks emerge.

9. Review and Update Plan

This DPIA will be reviewed periodically and updated if there are significant changes in the scope of the study, data processing methods, or applicable legal requirements. A final review will be conducted after completion of the study, which is expected to last a total of 12 months.