

## AMENDMENT TO CLINICAL STUDY AGREEMENT

This Amendment to Clinical Study agreement is entered into as of .....<sup>18 January 2019</sup> (“Effective Date”) by and between Sorin Group Italia S.r.l., with registered office in Milan, via Benigno Crespi 17 (“Sponsor”) and Center of Cardiovascular Surgery and Transplantation Brno, with registered offices in Brno, Pekařská 53, 656 91, Czech Republic (“Institution”)

### WHEREAS

- (A) On February 27<sup>th</sup>, 2017, Sponsor and Institution entered into a Clinical Study agreement regarding the clinical study SURE-AVR (Sorin Universal REgistry on Aortic Valve Replacement), clinical study plan numbered [REDACTED] (“Agreement”).
- (B) The Parties now wish to herein amend the Agreement, in order to integrate the compensation with a fee for completed cardiopulmonary case report forms of patients enrolled since May 12<sup>th</sup>, 2018.

**NOW THEREFORE**, the Parties agree as follows

1. Section **8.Compensation** of the Agreement is herein amended so as to read in its entirety as follows:

*8.1 Compensation. “The Sponsor will pay the Institution in accordance with Appendix 2. Any modifications to amounts set forth on Appendix 2 shall be binding on the Parties only after such modifications are reduced to writing and signed by the Parties. The Parties acknowledge that the compensation set forth on Appendix 2 is reasonable compensation, representing fair market value for the work performed by the Institution and has not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between Institution and Sponsor and that none of Institution, Investigator or any other Institution personnel have received any other compensation or inducement in connection with this Agreement or their participation in the Clinical Study. Institution acknowledges and agrees that payments made pursuant to the terms of this Article 8 represent the Sponsor’s total obligations under this Agreement. It shall be the responsibility of the Institution to make the appropriate agreed pass-through payments to the Investigator.”*

Appendix 2 has been modified so as to include 2584 CZK for Cardiopulmonary Bypass System form at surgery only for patients enrolled since May 12<sup>th</sup>, 2018.

Data Set	Compensation / patient (CZK*)
Cardiopulmonary Bypass System Data Set (Procedural)	(2584)

\*Based on the conversion rate on June 21st, 2018 : 1.00 EUR = 25,8378 CZK.

2. Unless otherwise indicated in this Amendment, the Agreement is unchanged.

**Sorin Group Italia S.r.l.**



Date: 18 January 19

**Center of Cardiovascular Surgery and  
Transplantation Brno**

