Product Combination Agreement

1 Parties

This covenant has been agreed between *PATRON Bohemia a.s.,* hereinafter referred to as Party A and James Leckey Design Ltd, hereinafter referred to as Party B.

2 Duration

This agreement starts on 15/03/2021 for an undefined period of time and can be ended by each of the parties by the end of each month taking in account a 3 month notice period.

Termination is deemed not to prejudice the mutual compatibility of the chairs who were delivered during validity period of the combination agreement, unless this is expressly motivated in the termination.

3 Products

This combination agreement refers to the products listed in the table in Appendix 1 (hereinafter: the Products). The table also shows the (mutual) compatibility. The (mutual) compatibility has been recognized and substantiated by the parties in the manner that the laws and regulations and prescribe applicable (harmonized) standards. Any special features such as exclusions of products in which there are no compatibilities, are also included in the table. The parties may, if necessary, add further substantiation in annexes or by other appropriate means. The parties will keep this table (and any attachments or other substantiation) up to date together.

4 Active information obligation

The parties will keep each other informed of changes and possible recalls in the products which have (potential) consequences for mutual compatibility. At least annually, the parties will evaluate the compatibility and agreements in this covenant. The parties will inform stakeholders of the (mutual) compatibility and the scope of this combination agreement.

5 Procedure in case of incidents

If an incident occurs with a combined product, the parties will inform each other and prioritize the importance of safety and research. They will together and in a professional manner investigate the incident adequately and prosperously. As far as reasonably possible, parties will provide each other the relevant information. The parties choose to make one secretary so that third parties have one point of contact, namely James Leckey Design Ltd. These agreements do not prejudge liability aspects vis-à-vis third parties and / or between parties.

6 Signature

Date: 24/02/2021
Name: Nicholas Freeburn
Function: Head of Product Management

Date: 24/02/2021
Name: Jiri Kotik
Function: Commercial Director

Appendix 1: Declaration

We PATRON Bohemia a.s. and James Leckey Design Ltd, declare under our joint responsibility that the product(s) combination to which this declaration relates are in accordance with the Medical Device regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. Specifically, the clauses related to the combination of medical devices:

REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

14. Construction of devices and interaction with their environment

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

23.4. Information in the instructions for use

The instructions for use shall contain all of the following particulars:

(q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment;

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;

6. PRODUCT VERIFICATION AND VALIDATION The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity

of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.2. Additional information required in specific cases

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

We also declare that the materials used in the manufacture of the following products follow the general principles of
ISO 14971 Application of risk management to medical devices.
And comply with the following standards:
EN 1021-2 and/or ISO 8191-2: Furniture – Assessment of ignitability of upholstered furniture
EN ISO 10993-5: Tests for in vitro cytotoxicity
In addition to any relevant harmonized standard to the MDR

We declare that the 'combined product' does not hold its own CE Technical file but we have and will maintain a CE Technical file(s) for our device(s) listed in Appendix 2, to comply with the Medical Device Regulation (EU) 2017/745.

Appendix 2: Products and Exclusions

Party A		Details	Party B		Details
Product	*Number*		*Product*	*Number*	
Chassis TOM5-CSI (MedDev.CZ.Reg.No. 00602095) Version: T5SWKPYYL	T5SWKPYYL	Chassis with chaassis/seat interface, size STD	Squiggles Seat	120-818 120-818-MIN	Squiggles Seat Shell.
Chassis TOM5-CSI (MedDev.CZ.Reg.No. 00602095) Version: T5SWKPS2L	T5SWKPS2L	Chassis with chaassis/seat interface, size SM42	Mygo Seat Size 1 Only	117-610 117-613 117-611 117-612 117-610-G 117-613-G 117-611-G 117-612-G	Mygo Seat Shell Size 1 configured with/without dynamic backrest and with/without grey metal.

Appendix 4 – Mounting/Combining/limitation instructions

Products that can be combined are limited to the one listed in Appendix 3, and may include accessory options such as covers and harness. No other sizes of Mygo Seat other than Size 1 shall be used.

Appendix 5 – Test reports

Static stability table ISO 7176-1 Squiggles

Static stability table ISO 7176-1 Mygo 1 Pa

S16409 Summary.pdf

19-034 JLD Test 1 Mygo-Patron 26-09-2

LTR-000-593 - Static Stability Mygo 1 Patrc

LTR-000-598 - Static Stability Squiggles Pat

Appendix 6 - QAA

QUALITY ASSURANCE AGREEMENT

The Quality Assurance Agreement is submitted to PATRON Bohemia a.s., herein and thereafter known as ”Party A”. This agreement defines the minimum quality assurance requirements required to finalize a combination agreement with “Party B” (“Party B” , as part of Sunrise Medical company) . Party A acknowledges that the Terms and Conditions of this Agreement are to be considered supplemental to those of any Sunrise Medical Purchase Order. For the terms of this Agreement Party A should maintain ISO 9001 or ISO 13485 certification or FDA facility registration (if applicable), and ensure all sub-suppliers maintain an effective quality management system. By signing the Combination Agreement, Party A also acknowledges their acceptance of the Terms and Conditions of the Sunrise Medical Quality Assurance Agreement, as defined herein:

1. Quality and Quality Assurance:

Party A shall only manufacture the Products utilizing medical-grade raw materials. Party A shall be responsible for the quality and purity of the raw materials and that they are fit for use in medical devices. All Products supplied to Sunrise will be designed, documented, manufactured and inspected in accordance with appropriate regulatory requirements for the markets in which the Products will be sold.

Party A shall promptly inform Sunrise about significant changes in the quality management system and the status of certification.

If any regulatory authority, reports from the field, or Party A, reveal a significant nonconformance with regulatory requirements regarding the work of Party A related to the Products and/or the Combination, Party A shall promptly inform Sunrise thereof and disclose the facts.

Party A shall comply with facility listing and registration requirements of national government authorities for all products listed in Appendix 2.

2. Regulatory Compliance:

2.1 Party A shall fully comply with the regulations of the current version of the MDD and of the current version of the MDR. Party A shall help Sunrise Medical to comply with these laws in any way possible, in particular by providing information and by cooperating with Sunrise Medical (e.g. regarding information and other requests by authorities).

2.2 For each Combination, Party A shall provide, in a timely manner, such assistance and information as Sunrise Medical reasonably requests to fulfill its regulatory obligations for each Combination. Party A shall in particular (i) keep and maintain a record of all customer complaints and claims brought to Party A's attention relating to any combination listed in Appendix 2; (ii) notify Sunrise Medical upon receipt of any information with respect to any Party A Product listed in Appendix 2 that indicates a possible safety concern that could have a material adverse effect on the safety or efficacy of the Combination listed in Appendix 2 or any product into which the Combination is incorporated, and of any field action regarding that Combination and combinations similar to the Combinations listed in Appendix 2 supplied by Party A to other customers; and (iii) otherwise cooperate by conducting investigations, providing information and analysis and conducting such follow-up activities as reasonably requested by Sunrise Medical.

2.3 Each party shall fully cooperate with the other party in dealing with customer complaints or claims concerning the combinations and shall take reasonable action in their area of responsibility to promptly resolve and follow-up regarding such complaints or claims. In particular, Party A shall provide investigation results as well as corrective and/or preventive action for all complaints or claims related to Party A's activities without undue delay.

2.4 Each party shall fulfill its own regulatory obligations to notify the competent authorities under the applicable national medical devices vigilance system.

2.5 If at any time after acceptance of a Purchase Order by Party A or delivery to and/or acceptance of the Product by Sunrise Medical, all or any of the Products become subject to a voluntary or involuntary recall by any government agency or corrective action by Party A, Party A shall assume responsibility and costs for implementing and complying with such a recall, including costs arising from the return and/or replacement of such Products, if the Products do not conform to the requirements of the applicable laws (in particular the MDD/MDR regulations). Party A shall credit or reimburse Sunrise Medical for all costs of recalled Products and any costs or losses incurred by Sunrise Medical as a result of such recall.

3. Engineering Change:

Any change to the Product should be communicated in written form to Sunrise Medical prior to first deliveries of product.

The parties will evaluate if the changes led to a modification of the combination documentation especially in regards to Risk Management, and take the appropriate measures.

3.1 The parties shall support each other in the risk analysis process by reviewing experiences gained from devices in the post-production phase.