






CHOICE BIOTECH


 Self-developed software

 more than 20 years experiences

 TFDA QMS certified factory

 ISO 13485:2016 certification

 Class II medical devices (software & CA product)

 FDA 510(k) Premarket Notification





OEM Business Model in JP

ISO 13485 certification factory

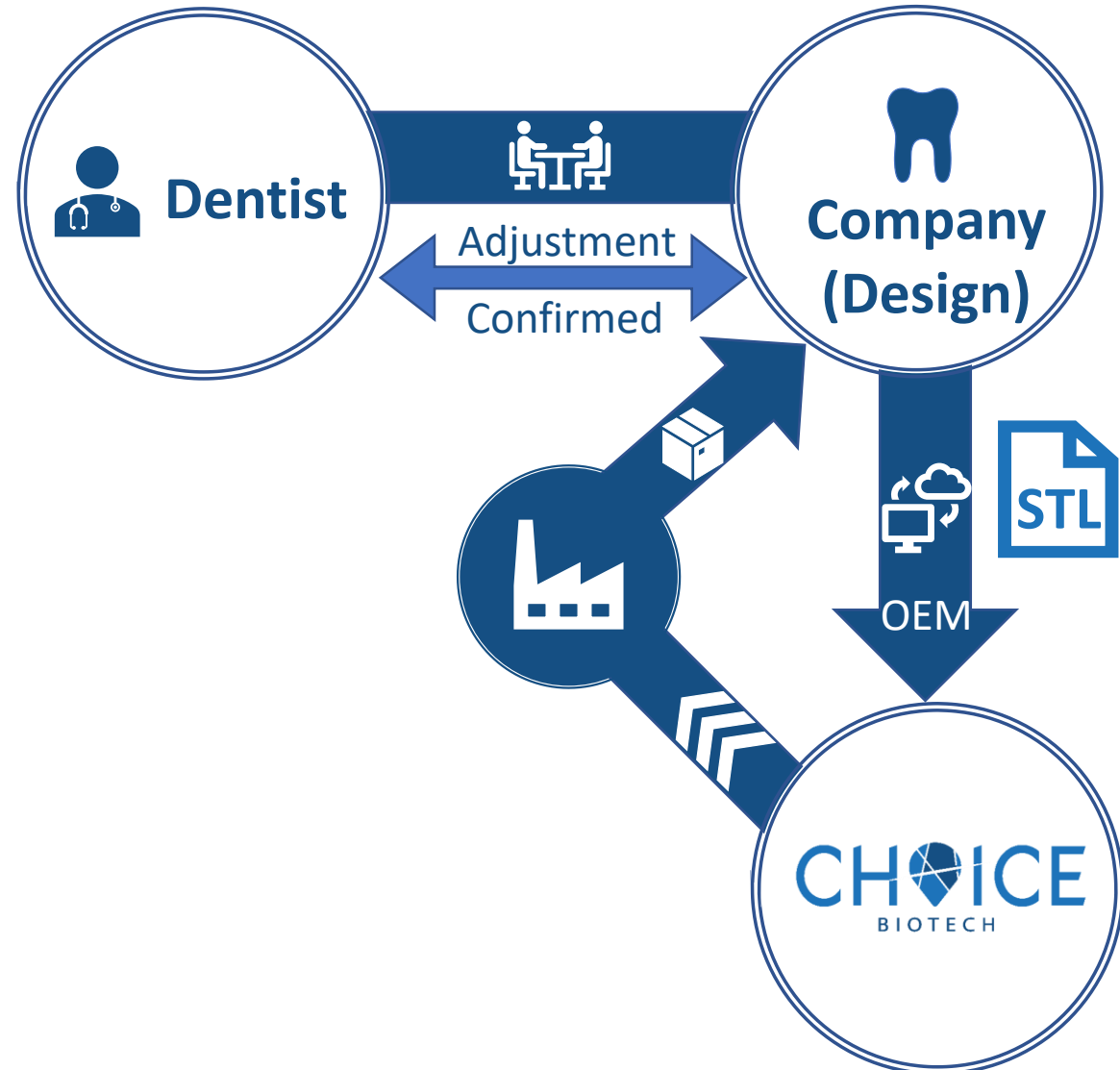
Directly output semi-finished medical materials and send to Japan for further product packaging.

High degree of freedom

According to your company's design habits, we accept a variety of design.

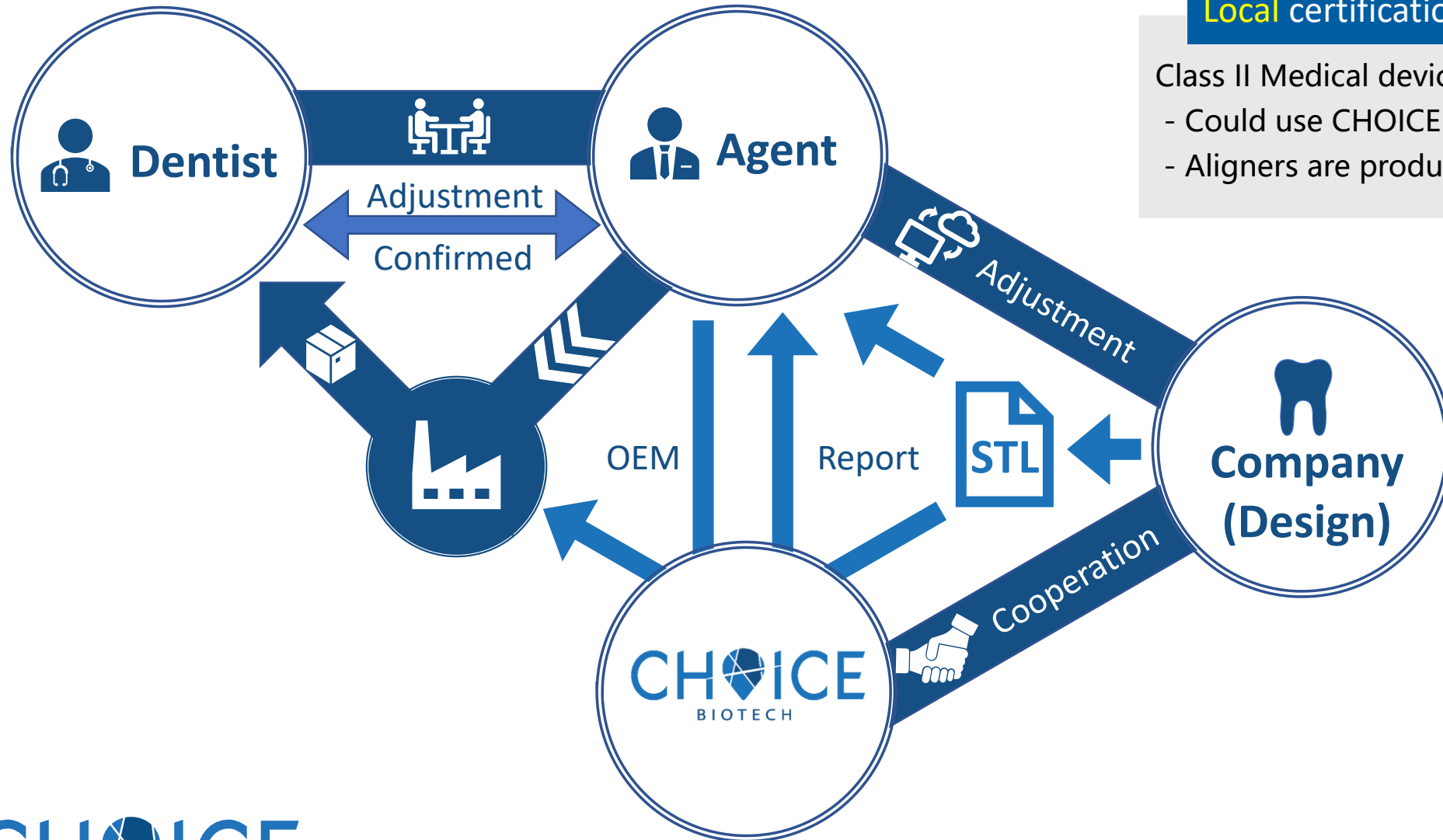
Stable and reliable

Medical device grade production quality





OEM Business Model in Taiwan



Local certification in Taiwan

- Class II Medical devices: Clear Aligner System
- Could use CHOICE software in Taiwan
- Aligners are produced and shipped directly



ODM & OEM Business Model SOP



Data collection

Patient case data

- Scan data/intro-oral scan data (STL)
- Oral/facial Photo
- Pano X-ray/ lateral cephalogram

Initial Indication

- Tooth extraction
- Molar/ canine relationship
- Attachment / IPR treatment



Cast data, Initial facial and intra-oral Photographs, Panoramic X-ray and lateral cephalogram image.



Treatment Design

The Orthodontic setup will be designed based on patient case data, including:

- Setup result (STL / Web viewer)
- Treatment time (Number of aligners)
- Analysis (Bolton ratio, each tooth movement/ rotation data)
- Cephalometric analysis (if needed)



We use self-developed treatment design Software - PlaniMax to control tooth movements, simulations, and alternative treatment scenarios.



Communication

Doctor makes the final decision

- Confirmation of treatment
- Control of timing
- Remind patients (22 hours/day)
- Refinement
- Attachment / IPR treatment
- Gingival margin design of aligner



The PET-G system we suggested can increase the comfort of patients and reduce the cost. The timing and frequency of changing aligner are crucial features of efficiency and a successful aligner treatment.

Usually Refinement is required 30% of number of aligner sets.

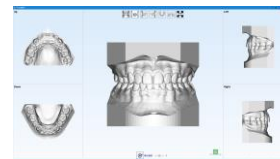
"Refinement" is the basis for controlling the precision of an envisaged treatment goal. The assessment of precision of the predicted treatment goal and therefore the used aligner system was based on the frequency of needed refinement (number of aligner sets) to achieve the promised treatment goal.



Export

The export files of each stage according to the treatment plan decided by the doctor and patient:

- Model (Number of aligners)
- Web viewer (keep track of the progress of each dental case)
- Initial/Final Study Model



Manufacturing

SOP in CHOICE factory

- 3D Printing
- Vacuum Forming
- Cutting
- Deburring
- Clean
- Pack and ship



Software + Service + Products

