Declaration of Conformity

Manufacturer: ***T&L(Jiaxing) Co., Ltd.***
4F, No. 159-1, Chenggong Road, Huimin Street, Jiashan, Jiaxing, Zhejiang, China.
Zip Code: 314100

European Representative: ***Obelis S.A.***
Bd. Général Wahis 53 1030
Brussels, Belgium

SRN No.:

Name of device: ***Orthopaedic Casting Tapes***

Brand Name: ***Cellacast Active, Cellacast Xtra, Cellacast Soft***

Model: ***See Attachment 1***

Basic UDI-DI: ***69435980***

Product Picture: ***See Attachment 1***

Start date of CE Marking: ***See attachment 1***

CE

Classification ((MDR, Annex VIII): ***Class I***

We here with declare exclusively under sole responsibility that the above mentioned products meet the provisions of the Medical Device Regulation (EU) 2017/745 for medical devices. All Supporting documentation is retained under the premises of the manufacturer.
Medical device is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Regulation

General applicable regulation: *Medical Device Regulation (EU) 2017/745*

Standard: ***See Attachment 2***

Conformity Assessment Route: Annex IX Chapter I

Place: T&L(Jiaxing) *Co., Ltd., KOREA*
Date: July 21, 2021

Signature: Y. S. Choi
Full Name: *Choi, Yoon-So*
Position: *President*

TNL-NDOC-MDR-1000 2021.07.21(Rev.1)

Attachment 1

List of CE Marked Product

PRODUCT NAME : Cellacast Active, Cellacast Xtra, Cellacast Soft

ISO 13485 Certificate No. : 35964

Document Owner : T&L(Jiaxing) Co., Ltd.

1) Cellacast Active

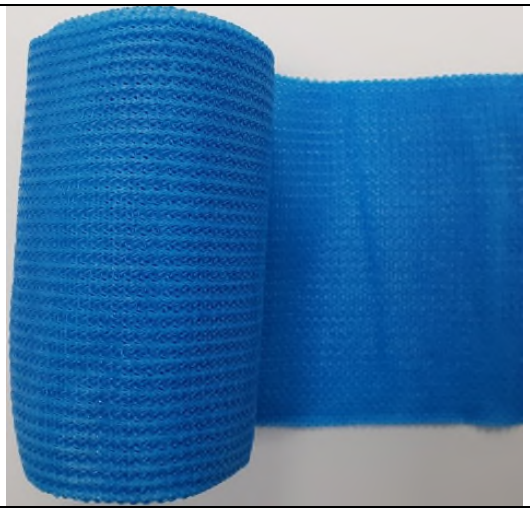
No.	Model	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	MD Code	Start of CE Marking
1	139876	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
2	139877	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
3	139878	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
4	139879	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
5	139880	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
6	139881	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
7	139882	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
8	139883	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
9	139884	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
10	139885	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
11	139886	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
12	139887	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
13	139888	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
14	139889	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
15	139890	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
16	139891	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
17	139892	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
18	139893	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021

2) Cellacast Xtra

No.	Model	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	MD Code	Start of CE Marking
1	139850	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
2	139851	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
3	139852	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
4	139853	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
5	139854	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
6	139855	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
7	139856	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
8	139857	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
9	139858	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
10	139863	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
11	139864	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
12	139865	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
13	139859	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
14	139860	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
15	139861	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
16	139867	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
17	139868	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
18	139869	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021

3) Cellacast Soft

No.	Model	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	MD Code	Start of CE Marking
1	139680	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
2	139681	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
3	139682	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
4	139683	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
5	139684	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
6	139685	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
7	139686	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
8	139687	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
9	139688	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
10	139689	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
11	139690	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
12	139862	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
13	139870	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
14	139871	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
15	139872	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
16	139873	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
17	139874	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021
18	139875	I	Annex VIII Rule 1	Annex II & III	33056	MD 0103	May 2021



Orthopaedic Casting Tapes

Prepared by Wang Xiaoyuan
Xiaoyuan Wang

Approved by
Ja-Hak Koo

Attachment 2

European Harmonized Standards supporting Technical Files;

Document Number	Title of Document
ISO 13485:2016	Medical devices-Quality management system-Requirements for regulatory purposes
ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part1: General requirements
BS EN 1041:2008+A1:2016	Information supplied by the manufacturer with medical devices
BS EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
MEDDEV 2.7/1 revision 4 June 2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/1 revision July 2019	Guidelines on a medical devices vigilance system
Regulation(EU) 2017/745	European parliament and of the council of 5 April 2017
Standard of T&L Co., Ltd. Related Orthopaedic Casting Tapes	