

DECLARATION OF CONFORMITY

Hartwell Medical LLC
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SRN: APP000007092

Type of Device: Scoop Stretcher/Extrication Board

Device Name: CombiCarrierII®

Basic UDI-DI: 0850012936CC7G

Model Numbers: CC 2200P CC 2200PY
CC 2200P-DT CC 2200P-OD

Accessories: CC 3400H
CC 3400H-BK

Parts: CC 2100-9-400 CC 3400-9-100 CC 3400-9-100-BK
CC 2100-9-350 CC 3400-9-200 CC 3400-9-200-BK
CC 3400-9-300 CC 3400-9-300-BK

Intended Purpose Stabilization of the body during extrication, transfer, and transport.

Risk Class I (Annex VIII, Rule 1)

Conformity Assessment Route Annex IV
Self Certification

EC Representative Emergo Europe (SRN: NL-AR-000000116)
Prinsessegracht 20
2514 AP The Hague
The Netherlands

We herewith declare that the above-mentioned products provided with CE marking meet the General Safety and Performance Requirements of Regulation 2017/745. This declaration is issued under the sole responsibility of Hartwell Medical LLC.

Attested this 1st day of July 2021 at Hartwell Medical LLC in Carlsbad, California.



Gary R. Williams
President and CEO