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vaš znak / your ref.: OSV/6104
naš znak / our ref.: 2021-12-15
datum / date:

Maureen Miller
Ortho Solutions LC dba DynaFlex
8050 Hawk Ridge Trail, Lake St. Louis

63367-2204 MISSOURI

Subject: Statement on the non-significant change regarding transitional provision under Article 120 of the MDR and additional notice to the certificate MDD-146

SIQ Ljubljana (NB 1304) hereby confirms that the

Ortho Solutions LC dba DynaFlex
8050 Hawk Ridge Trail, Lake St. Louis

63367-2204 MISSOURI
USA

informed SIQ Ljubljana on the new address and provided all necessary documentation regarding the change (Notice of change, MDD DN022, 2021-07-28).

Slovenian Institute of Quality and Metrology (NB 1304) conducted the ISO 13485:2016 partial surveillance audit (Audit report OSV 01280/2021 dated 2021-10-29) and MDD 93/42/EEC surveillance audit with ISO 13485:2016 re-certification audit (Audit report OSV 01443/2021 dated 2021-11-30) at the new site and hereby confirms that the organization's change is non significant.

SIQ Ljubljana as a certification and Notified body regularly checks whether an EC certificate holder meets the requirements of the Medical Device Directive 93/42/EEC by surveillance audits at least once a year.

On the basis of Notice of change (MDD DN022, 2021-07-28) and the performed audit, SIQ Ljubljana hereby issues an additional notice to the current Certificate MDD-146 and Detailed list of product names, models, and types annexed to the certificate MDD-146, version 01, issued on 2019-10-10 (valid until 2024-05-27):

Data of the certificate:

| | |
|---------------------|---|
| EC Certificate No.: | MDD-146 |
| Issued to: | Ortho Solutions LC dba DynaFlex 8050 Hawk Ridge Trail, 63367 Lake St. Louis, Missouri, USA |
| Place of production | Different OEMs, see below |
| Product category: | Orthodontic Brackets, Bands & Tubes |
| UMDNS: | 16360, 16198, 16199 |
| Product category: | Orthodontic Archwires, Wires, Springs |
| UMDNS: | 16204 |
| Product category: | Orthodontic Elastomeric Products |
| UMDNS: | 16190 |
| Standard: | MDD 93/42/EEC |
| Annex: | V |