

29.3.2017

A8-0068/2

Amendment 2

Joëlle Mélin

on behalf of the ENF Group

Recommendation for second reading

A8-0068/2017

Glenis Willmott

Medical devices

10728/4/2016 – C8-0104/2017 – 2012/0266(COD)

Council position

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Proposal for rejection

***The European Parliament rejects the
Council position at first reading.***

Or. fr

Justification

The new regulation disproportionately toughens the conditions for notified bodies and European in the medical devices sector. It therefore risks causing the disappearance of many small businesses in favour of third country companies, thus seriously impacting on the sovereignty of the Member States in health matters. Finally, it transfers responsibility from national authorities to notified bodies in an unacceptable manner.